

Exhibit 1



**SUPERIOR COURT OF NEW JERSEY
LAW DIVISION, ATLANTIC COUNTY**

BRANDI CARL,

Plaintiff,

v.

JOHNSON & JOHNSON, et al.,

Defendants.

DOCKET NO. ATL-L-06546-14

**TALC-BASED POWDER
PRODUCTS LITIGATION
CASE NO. 300**

CIVIL ACTION

DIANA BALDERRAMA,

Plaintiff,

v.

JOHNSON & JOHNSON, et al.,

Defendants.

DOCKET NO. ATL-L-6540-14

**TALC-BASED POWDER
PRODUCTS LITIGATION
CASE NO. 300**

CIVIL ACTION

EXPERT REPORT OF KATHLEEN M. SUTCLIFFE, PH.D.

April 12, 2024

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*Confidential***I. QUALIFICATIONS**

1. My name is Kathleen Sutcliffe, and I am a Bloomberg Distinguished Professor at Johns Hopkins University, with appointments in the Carey Business School, School of Medicine, School of Nursing, and Bloomberg School of Public Health. Prior to joining the faculty at Johns Hopkins University, I was on the faculty at the Stephen M. Ross School of Business at the University of Michigan for more than twenty years. I hold a Ph.D. in Organization Theory and Behavior from the University of Texas at Austin, a Master of Nursing degree from the University of Washington, a B.S. from the University of Alaska, and a B.A. from the University of Michigan. I am a member of the Academy of Management ("AOM"), the European Group for Organizational Studies ("EGOS"), the Institute for Operations Research and the Management Sciences ("INFORMS"), and the Strategic Management Society. I also hold a seat on the Committee on Emerging Trends in Aviation Safety for the Transportation Research Board of the National Academies of Science, Engineering and Medicine.
2. In my research, I seek to understand organizational adaptability, reliability, and resilience. In one stream of work, I focus on top executive teams and group dynamics, including information search processes, communication, and learning processes, and how these elements affect firm performance. In a second stream of work, I investigate organizational reliability, particularly how an organization's design and culture influence its members' abilities to sense, cope with, and respond to unexpected and changing demands. I also investigate factors that enable organizational and individual resilience. Particularly relevant to the issues in this matter, I have conducted retrospective studies and assessments of organizations across decades of research. This research is designed to understand many facets of organizational behavior, including:
 - 1) how organizations manage risks, crises, and make decisions under uncertainty;
 - 2) how organizations process and make sense of ambiguous and equivocal information;
 - 3) how organizations shape safety culture;
 - 4) whether the culture of an organization encourages employees to speak up when they have a concern; and
 - 5) how organizations are designed to prioritize safe and reliable performance, including whether they comply with rules and safety norms.My research has been the basis of several highly cited methodologies and frameworks used to assess organizational behavior and decision-making.

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3. I have investigated these issues in many organizational contexts, including in healthcare, where I have examined the systemic/organizational origins of medical mistakes and factors that affect the capabilities to catch, correct, and cope with errors in high-risk, dynamic systems. I have worked with organizations in other “high hazard” industries, including wildland firefighting, national security, steel production, chemical processing, and oil and gas exploration. I have also conducted research and consulted to organizations in consumer-facing industries, including financial services, manufacturing, automotive, and transportation.
4. I have published my research in a wide range of academic and practice-related journals, such as the *Academy of Management Journal*, the *Academy of Management Review*, *Academic Medicine*, *California Management Review*, *Harvard Business Review*, *Human Relations*, *Organization Science*, *Sloan Management Review*, and *Strategic Management Journal*. In addition, I have co-authored/co-edited four books on organizational responses to risks. My published research includes organizational assessments of Toyota’s organizational design and sensemaking system as it pertained to the problem of its slow recognition of the unintended acceleration difficulties. I studied the problem of organizational mindlessness and sensemaking failures in contributing to Washington Mutual’s ultimate bankruptcy. I studied the problem of sensemaking failures that led firefighters to normalize small signs of danger, which led to the Cerro Grande fire in New Mexico’s Bandelier National Monument, with more than a billion dollars in damage. I studied the problem of a rigid cultural belief system at the Bristol Royal Infirmary in the UK, and the organizational and cultural factors resulting in excessive rates of pediatric cardiac deaths.
5. I have consulted to government agencies, such as the Department of Homeland Security, the Department of the Interior, the United States Forest Service, the Secretary of the Navy, the Air Force and Navy Surgeon Generals, the Fire Department of New York, and the Netherlands national rail agency, ProRail. I have applied my expertise in healthcare, including at Johns Hopkins Medicine and its associated hospitals and clinics, Mayo Clinic, Cincinnati Children’s Hospital and Medical Center, and Northwestern Medical School and Memorial Hospital. I have also advised private multinational firms in my consulting work. For example, I worked with ThyssenKrupp (now thyssenkrupp) and a team of employees from multiple business units (e.g., steel, elevator, information services, etc.) with a general goal to reshape the organization’s processes and practices to enhance its safety, quality, and reliable performance. To do this, we analyzed units’ existing organization (e.g., communication and information practices, management structures, processes, behaviors, and cultures) and its effects on the nature of existing issues and performance challenges. In addition to conducting a series of workshops with top executives and other relevant organizational members (e.g., safety experts), we

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worked with other unit members to facilitate the conduct of event analyses, culture evaluations, and planning and assessment of practical improvement actions. I was directly involved in the implementation of solutions and the organization's efforts to check the impact of change and improvements and measures of quantitative and qualitative success.

6. I have taught courses on organizational behavior and organizational theory, human behavior and organizations, leading and managing change, power and politics, and organizational learning and "sense making" in executive education, graduate, and undergraduate classes at Johns Hopkins University, the University of Michigan, and the University of Minnesota.
7. I have provided keynote addresses and training workshops around the world to leadership teams and to industry and professional groups such as Goldman Sachs, Georgia Pacific, Bombardier's annual Safety Standdown, the Council for Engineering and Scientific Societies, the Canadian Anesthesiologists' Society, and the European Society for Anesthesiology. Before studying for my doctoral degree, I served as Director of Health and Social Services for the Aleutian Pribilof Islands Association (one of the twelve regional Alaska Native Corporations) and served as a program manager for the State of Alaska.
8. My current curriculum vitae, which includes a complete list of my publications, is attached to this report as **Appendix A**. A list of my testimony in the last four years is contained in **Appendix B**.

II. ASSIGNMENT

9. I have been asked to assess what Johnson & Johnson ("J&J")¹ knew – and when – about the alleged presence of asbestos in its cosmetic talc products, and what actions it took to acquire this knowledge.² In addition, I have been asked to assess the extent to which J&J's actions were consistent with an organizational commitment to the wellbeing of consumers. In order to conduct this assessment, I have examined industry, regulatory, scientific, and media perspectives on whether cosmetic talc contains asbestos, and how

¹ Responsibility for J&J cosmetic talc products has changed over time. Throughout this report, I will use "Johnson & Johnson" or "J&J" to refer to both current and past iterations of the relevant company for ease of reference.

² The general term "baby powder" is used throughout my report to reference cosmetic talc products manufactured and sold by J&J, including Johnson's Baby Powder and Shower to Shower.

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these perspectives changed over time.³ I have examined internal J&J documents from the ordinary course of business to understand how J&J's perspectives on these questions were discussed, disseminated, and acted upon. I have also examined J&J's organizational priorities, core objectives, and commitment of resources to assess consistency between J&J's actions, its organizational focus, and a commitment to consumer wellbeing.

10. I have decades of experience and expertise with similar assignments and approaches. I have employed this type of approach – establishing an understanding of the starting situation, analyzing particular decisions or events, and assessing the broader organizational context in which they are occurring – to draw conclusions about potential inconsistencies, concerns, and failures. I have also employed this approach to highlight best practices, opportunities, and improvements. I have been asked to answer questions retrospectively (“what could the organization have done better”) and prospectively (“what can we do to anticipate and prevent future problems”). Answering these questions in a rigorous and scientific way requires expertise in the established discipline of organizational theory and real-world experience in understanding the complexities and uncertainties organizations face. It requires knowledge of how an organization operates in the ordinary course of operations, and in extraordinary circumstances that disrupt the status quo. I have applied my expertise along all of these dimensions in the assessment conducted here, and my conclusions are based on the same.
11. A list of the materials that I have reviewed and assessed in undertaking my assignment is attached as **Appendix C**. Others at Analysis Group, Inc. working under my supervision and direction have assisted me in this matter. I am being compensated at a rate of \$1,100 per hour. My compensation is not contingent upon the outcome of this case. My work in this matter is ongoing, and I reserve the right to update my opinions to the extent new information becomes available to me.

III. SUMMARY OF OPINIONS

12. I was retained by J&J to provide an expert opinion in connection with the above-captioned matters. Plaintiffs claim the use of J&J's talc-based baby powder caused Ms. Carl and Ms. Balderrama to develop ovarian cancer. Plaintiffs further allege that J&J has known for decades that the talc in its baby powder may pose health risks to consumers, and that J&J ignored and covered up these health risks. These claims revolve around the questions of whether J&J's baby powder was contaminated with asbestos or was

³ My review of the evidence is through the lens of an expert in organizational behavior and theory and not through that of an epidemiologist or regulatory expert. Therefore, I am not offering any opinions with respect to any epidemiological issues, including the alleged association between talc and ovarian cancer, or any regulatory processes, including the identification of potential carcinogens.

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otherwise unsafe to use, and whether J&J did enough to warn users of the alleged health risks.⁴ **See Section IV.A.**

13. Over the past five years, I have been engaged in research regarding what J&J knew, and when, regarding the presence of asbestos in its baby powder. In conducting this research, I have employed an established research methodology and highly cited framework to review an extensive record related to these allegations. Decades of research on organizations, including my own, informed the methodologies and frameworks that I employed in this research. Researchers in the field of organization science are specially trained to employ these methodologies and frameworks to assess organizations. **See Section IV.B.**
14. Based on this research, it is my professional opinion that J&J actively pursued knowledge regarding the potential health risks associated with its baby powder, consistent with the incentives, motivations, and actions of an organization committed to the wellbeing of consumers. The record I reviewed describes this active pursuit. In the early 1970s, J&J engaged with consumers, regulators, scientists, the media, other manufacturers, suppliers, and trade organizations to make sense of new scientific knowledge and competing perspectives. This engagement demonstrates J&J's commitment to a scientific understanding and articulation of the potential for asbestos in talc, and the health effects of exposure to asbestos and/or talc. **See Section IV.C.**
15. J&J's subsequent actions have reflected its commitment to testing and validating scientific knowledge and resultant understanding. J&J has committed significant resources to developing and implementing industry-leading methods for testing its talc sources and its baby powder for the presence of asbestos. J&J has also committed significant resources to continued discussion, validation, and dissemination of scientific knowledge among researchers and external stakeholders. In my opinion, J&J's actions exemplify its longstanding commitment to putting consumer wellbeing first. J&J's perspective that its baby powder does not contain asbestos is based on scientific knowledge it has acquired, discussed, validated, and disseminated over decades of testing and research. **See Section IV.C.**
16. J&J's active pursuit, testing, and validation of knowledge regarding the potential health risks associated with its baby powder reflect best practices in organizational sensemaking. Sensemaking enables organizations to understand, articulate, and act on

⁴ See Plaintiffs' Amended Complaint and Jury Demand, *Brandi Carl and Joel Carl v. Johnson & Johnson et al.*, Docket No. ATL-L-006546-14, Atlantic County Superior Court, April 7, 2021; Plaintiffs' Amended Complaint and Jury Demand, *Diana Balderrama and Gilbert Balderrama v. Johnson & Johnson et al.*, Docket No. ATL-L-006540-14, Atlantic County Superior Court, April 7, 2021.

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knowledge in ways that are consistent with organizational perspectives and priorities. J&J's organizational perspectives, priorities, and core objectives are embodied in the J&J "Credo." The Credo states that J&J's "first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services." J&J's public statements, its internal policies and procedures, evidence from the ordinary course of business, and interviews with current and former employees all indicate that the Credo is top of mind and drives actions and behaviors at J&J. It is my opinion that J&J's actions with regard to the alleged presence of asbestos in its baby powder reflect the commitment articulated in the Credo and its decisions indicate that the Credo was top of mind. Put differently, J&J's actions and decisions have been, and continue to be, consistent with the actions of a responsible company that prioritizes the wellbeing of consumers.

17. As an expert in organizations and the methods by which they employ sensemaking to prioritize reliability and safety, it is my opinion that J&J's actions are consistent with behaviors I would expect to see in an organization that prioritizes consumer wellbeing. It is also my opinion that J&J's actions are inconsistent with behaviors that indicate carelessness or disregard for the same. Allegations that J&J "knew" or hid the "truth" about the alleged health risks associated with its baby powder are inconsistent with the record of J&J's actions, decisions, and organizational commitment to the wellbeing of consumers. In summary, it is my opinion that J&J:

- Demonstrated an early commitment to safety and purity of its baby powder products;
- Actively investigated and responded to concerns about the safety of its baby powder products;
- Engaged with industry and regulatory stakeholders and was transparent with them regarding the safety of its baby powder products; and
- Relied on scientific knowledge and evidence, including a rigorous testing program, to verify the safety of its baby powder products.

18. I expand upon these opinions and explain the bases for them in the remainder of this report.

IV. OPINIONS

A. Plaintiffs' Conclusions and Opinions about Johnson & Johnson as an Organization Are Biased, Rely on Speculation, and Present a Flawed Causal Narrative

19. Over the past five years, I have been engaged in research regarding what J&J knew, and when, regarding the presence of asbestos in its baby powder. As part of this research, I have reviewed arguments from plaintiff lawyers and testimony from their experts that present a narrative asserting that for more than six decades, J&J “hid” known associations between its baby powder and certain cancers. More specifically, I have reviewed various complaints, trial transcripts, and expert reports with respect to their statements and opinions regarding J&J as an organization.⁵ I have also specifically reviewed the reports submitted in this matter by Dr. David Kessler and Dr. George Newman.⁶ Based on this review, I describe my understanding of plaintiffs’ narrative, and I explain why the resulting conclusions and opinions about J&J as an organization that have been offered by plaintiff lawyers and experts in the context of litigation are flawed. My opinions are those of an expert in organizational science. I do not offer opinions on any issues discussed by plaintiff lawyers or experts that lie outside of my expertise in organizational science.

1. Plaintiffs’ Causal Narrative

20. The testimony I have reviewed often begins with a brief history of J&J’s baby powder, which was introduced in 1894. This history typically describes the importance of J&J’s baby powder for the company and usually highlights a few marketing campaigns for J&J’s baby powder for context. The fact that J&J’s baby powder was an effective and successful product over many decades is not in dispute.
21. However, plaintiffs allege that at least since the 1950s, J&J was testing its talc because it was concerned about impurities that could be harmful to consumers’ health. Plaintiffs allege that there is evidence demonstrating that this testing indicated that tremolite, a type of asbestos, was found in J&J’s talc. Further, the narrative goes, these findings were discussed internally at J&J, but even though asbestos was already known to be a health

⁵ A complete list of the materials I have reviewed regarding the plaintiffs’ causal narrative is included in **Appendix C**.

⁶ Amended Expert Report of David Kessler, M.D., *In re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices, and Products Liability Litigation*, Civil Action No. 3:16-md-2738, United States District Court of New Jersey, November 15, 2023; Expert Report of George E. Newman, Ph.D., *In re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices, and Products Liability Litigation*, Civil Action No. 3:16-md-2738, United States District Court of New Jersey, November 15, 2023.

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hazard at that time, J&J did not raise any alarm regarding its baby powder externally. Instead, according to plaintiffs, J&J chose to conceal these findings from the public.

22. Plaintiffs also point to a research study conducted in 1971, to assert that there was “evidence” that talc particles were found in the tissue of women with ovarian cancer. Plaintiffs further assert that secondary testing by Mount Sinai School of Medicine confirmed talc in the same ovarian cancer tissue sample and found chrysotile asbestos in the sample as well.
23. Plaintiffs further allege that J&J manipulated asbestos testing results and that it reported those “manipulated” results to the FDA. Plaintiffs claim that J&J knowingly used tests that were not adequate to find asbestos in order to assert that no asbestos had been detected.
24. Despite all this manipulation, asbestos was still found in J&J’s cosmetic talc, according to plaintiffs. To support this claim, plaintiffs commonly point to a few examples of “evidence” of asbestos in J&J’s baby powder, including the findings of Mount Sinai’s Dr. Arthur Langer in 1971, the test results of Dr. Seymour Lewin, a chemistry professor at New York University, who was subsequently commissioned by the FDA, as well as an analysis by the Dutch Consumer Organization in 1973. According to plaintiffs, these results were again discussed internally at J&J, but no warnings were extended externally.
25. Plaintiffs also point to a 1982 study by Dr. Daniel Cramer to assert that he found a statistically significant link between genital talc powder use and ovarian cancer. Plaintiffs further assert that at that point, J&J had a statutory duty to warn consumers under FDA regulations. However, so the narrative continues, instead of warning consumers, J&J tried to intimidate Dr. Cramer to conceal the findings of his research, criticized Dr. Cramer’s findings as inconclusive, and went on to confirm, contrary to his findings, that J&J’s baby powder was safe.
26. Another series of events that plaintiffs point to revolve around a 1997 letter that was sent to J&J by Dr. Alfred Wehner, J&J’s own consultant. Plaintiffs allege that, in this letter, Dr. Wehner objected to proposed statements by the trade organization Cosmetic, Toiletries and Fragrance Association (“CTFA”) rejecting a potential association between talc and cancer. However, so the plaintiffs’ narrative continues, instead of acting on Dr. Wehner’s objections, J&J continued its long-standing campaign together with CTFA to intimidate scientists and to create doubt about the science.
27. Moreover, plaintiffs point to alleged unethical interactions with regulators. Plaintiffs assert that J&J alone, and in concert with others, successfully stopped the National Toxicology Program (“NTP”) from categorizing talc as a carcinogen. Plaintiffs further

allege that J&J attempted to interfere with the designation of talc as carcinogenic by the International Agency for Research on Cancer (“IARC”). According to plaintiffs, not only did J&J refuse to share the knowledge it had with consumers, but J&J made sure that no one else shared that knowledge, either.

28. Plaintiffs also point to a draft screening assessment on the safety of talc published by Health Canada in 2018 that suggests a potential causal link between perineal talc exposure and ovarian cancer. Plaintiffs go on to allege that, in response, J&J continued to defend its baby powder as asbestos-free and tried to prevent Health Canada from taking actions to remove talc-based products from the market. Nonetheless, so the narrative continues, Health Canada published its final assessment regarding the health risks associated with the genital use of talcum powder in 2021.
29. Plaintiffs further point to a 2019 episode involving the FDA and Mr. Andreas Salvidar, an expert J&J had hired for various litigation matters. Plaintiffs allege that Mr. Saldivar, now hired by the FDA, tested an off-the-shelf bottle of J&J’s baby powder and found chrysotile asbestos in 2019. Instead of accepting those results, so the narrative goes, J&J retested a “control sample” until it showed the desired negative result, and blamed any prior positive results on contamination. Plaintiffs assert that this series of events led to a “forced recall” of J&J’s baby powder in 2019, and ultimately a withdrawal from the U.S. market in 2020.
30. Finally, plaintiffs point to the fact that J&J had developed a cornstarch-based alternative to talc-based baby powder yet chose to keep its talc-based baby powder on the market despite alleged safety concerns. Plaintiffs assert that the cornstarch-based alternative was not introduced as a replacement for the allegedly unsafe talc-based powder, because it was not deemed as monetarily beneficial at the time.

2. Plaintiffs’ Conclusions About Johnson & Johnson as an Organization Are Flawed, as They Are Based on an Incomplete and Biased View of the Evidence That Is Not Grounded in a Scientific Framework

31. It is my opinion that plaintiffs’ conclusions about J&J as an organization based on the above causal narrative are flawed. Plaintiffs’ conclusions are based on an incomplete and biased view of the evidence that is not grounded in a framework for understanding it or a scientific approach to evaluating it. Many of plaintiffs’ sweeping statements are based on speculation and cherry-picked evidence that is taken out of context.
32. First, plaintiffs conclude that J&J had known for decades about test results showing that its baby powder contains asbestos and research studies linking its baby powder to cancer, and regardless of this knowledge, continued concealing “the truth” from the public and

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from regulators and marketing its products as pure and safe to consumers. In reaching this overarching conclusion, plaintiffs rely on selected portions of the record that are not representative of the record as a whole. They ignore evidence showing that J&J devoted significant attention and resources to clarify, interpret, and discuss new scientific knowledge regarding the identification of asbestos in cosmetic talc and a potential cancer link. Rather than concealing “the truth” as plaintiffs allege, J&J’s actions demonstrate its commitment to articulating and disseminating factually accurate scientific knowledge regarding the safety of its baby powder. J&J’s efforts to avoid public confusion were motivated by this commitment and are consistent with the incentives, motivations, and actions of an organization that prioritizes the safety of its products.⁷

33. Second, plaintiffs allege that despite being aware of the potential health hazards of its baby powder, J&J repeatedly lobbied against the regulation of talc and refused to add appropriate warning labels to its talc-based products. However, plaintiffs base these claims portraying J&J’s actions as adversarial to regulators on a mischaracterization of the record that, at times, goes as far as erroneously attributing statements made by non-J&J employees to J&J.⁸ Moreover, plaintiffs’ allegations disregard the fact that the FDA as the relevant regulatory body had considered and rejected both asbestos and ovarian cancer warning labels for talc on several separate occasions.⁹ A detailed review of the evidence shows how J&J repeatedly collaborated with regulators on developing new testing methods and quality control measures.¹⁰ In recent years, J&J has continued to collaborate with industry regulators in a cooperative effort to ensure that standards for talc and detection methods for asbestos are consistent with current scientific knowledge.¹¹
34. Third, plaintiffs conclude that, over the course of decades, J&J had attempted to confound the scientific literature by discrediting the findings of independent researchers, trying to intimidate them to prevent them from speaking publicly about their research findings on the health hazards of talc, and hiring consultant scientists to produce results supporting its public statements that its talc was free of asbestos as well as other health risks. These claims are not supported by the evidence in the record. In response to confusion around conflicting new scientific results on cosmetic talc in the early 1970s, J&J actively sought external knowledge to inform its understanding of the potential health risks of its baby powder. J&J employees worked with scientists to conduct

⁷ See Sections IV.C.2.a and IV.C.3.c.

⁸ See Section IV.C.4.b.

⁹ See Section IV.C.4.a.

¹⁰ See Section IV.C.3.a.

¹¹ See Section IV.C.4.b.

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additional research, and to follow up on related independent research. J&J's engagement with the scientific community demonstrates a continued and proactive response, consistent with the incentives, motivations, and actions of an organization committed to the wellbeing of consumers.¹²

35. Fourth, plaintiffs allege that J&J used asbestos testing methods that it knew were not sensitive enough to reliably detect asbestos, and used the resulting finding that asbestos was not detected as "evidence" that its talc was indeed asbestos-free. These claims are an oversimplification of the facts and replete with what is known in my field as "hindsight bias." Hindsight bias is the tendency to look back in time and judge past events without conscious recognition that the way one is viewing those events is biased by the fact that one knows the ultimate outcome or result. This is fundamentally different than the perspective in the moment, as the event was happening, and with limited foresight. In particular, plaintiffs' allusion to the inadequacy of J&J's asbestos testing in the early 1970s from today's standpoint is a typical example of hindsight bias. I avoid such bias in my analysis by instead evaluating J&J's efforts to identify and use appropriate testing methods with the limited foresight available at the time. Such careful review of the evidence in the record indicates that there was a lack of consensus around the identification of asbestos and testing procedures capable of identifying its presence in cosmetic talc in the early 1970s.¹³ In an effort to find consensus, J&J was actively engaged with regulators and other stakeholders to establish testing procedures capable of identifying the presence of asbestos in cosmetic talc, which resulted in the first industry testing standards.¹⁴ Moreover, J&J invested time and resources to refine its own testing methodology, which was more rigorous than that adopted by the industry.¹⁵
36. Fifth, plaintiffs conclude that J&J kept its talc-based baby powder on the market as it was invaluable as J&J's "golden egg," unlike the substitute cornstarch-based product that was likely safer. This conclusion is unsupported and based on mere speculation. When J&J approved Johnson's Baby Powder with Cornstarch for national sale in 1978, it was not introduced as a replacement for talc-based powders, because by that time much of the ambiguity and concern regarding the safety of cosmetic talc had been resolved.¹⁶ Similarly, the withdrawal of the talcum-based baby powder from the U.S. market in 2020

¹² See Section IV.C.3.c.

¹³ See Section IV.C.2.b.

¹⁴ See Section IV.C.3.a(1).

¹⁵ See Section IV.C.3.a(2).

¹⁶ See Section IV.C.2.c.

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was not “forced” but rather a voluntary J&J business decision entirely unrelated to its safety.¹⁷

37. For all of the above reasons, plaintiffs’ final conclusion that J&J prioritized profits over the health and safety of consumers is unsupported and incorrect. As I described above, plaintiffs reach these flawed conclusions in a number of ways. In some cases, plaintiffs distort the evidence. In other cases, they “cherry pick” evidence, relying on selected portions of the record that are taken entirely out of context or are not representative of the record as a whole. In other cases, they seemingly ignore relevant portions of the record. In still other cases, they reach their conclusions without citing any evidence at all.
38. To build their narrative that J&J knowingly risked the health and safety of consumers, plaintiffs focus on selected excerpts from a few documents while ignoring a wide array of evidence in the record. Instead, to adequately support their conclusions about J&J as an organization, plaintiffs would need a conceptual framework based in organizational theory to guide the research and analysis, and a scientific methodology for assessing the available documents and data. Conducting such an analysis is a complex task that requires training and experience in conducting assessments of organizations and their incentives, motivations, and actions. Below, in **Section IV.B.**, I describe the conceptual frameworks and scientific methodologies that I, and others with the requisite training and experience, use to conduct this type of assessment, and I describe how I have applied it in the context of my research and assessment of J&J. In **Section IV.C.**, I describe the outcomes of my assessment, and the opinions and conclusions about J&J, that resulted from this research.

**B. Understanding Organizational Incentives, Motivations, and Actions
Requires Training in Research Methods in the Field of Organizational
Theory and Behavior**

39. Decades of research on organizations, including my own, informs the methodologies and frameworks that researchers employ to assess organizations. Organizational assessments are regularly used to evaluate the degree to which an organization promotes mindful attention to organizational priorities. They often focus on past behaviors, decisions, structures, and norms in an effort to identify and correct any misalignment between these aspects of the organization and its stated priorities. These assessments can rely on evidence regarding organizational systems and processes, statements and actions, decisions and outcomes, or norms and culture. A robust assessment typically incorporates many types of evidence, and then employs a scientific and valid method to judge this evidence relative to hypotheses about whether an organization behaved in ways

¹⁷ See **Section IV.C.4.c.**

consistent with its priorities. The analyses are documented in detail and the results are replicable. Such an assessment is a complex endeavor that specially trained researchers in my field undertake. I have conducted these assessments in my own research in many different contexts, including as an expert witness. I have been asked to review and critique the assessments done by others hundreds of times. My perspective on how to appropriately conduct such an assessment, and how to then draw appropriate conclusions based on that assessment, is based on decades of experience of actually doing such assessments.

40. “Good science” in the field of organization science involves a careful analysis by a trained researcher. It is replicable by other researchers, because the framework, methodology, and evidence are carefully assessed and fully described and documented. It avoids cherry-picking, bias, inappropriate extrapolation, and broad generalizations about organizations, as these practices undermine the validity of conclusions and, when left unchecked, undermine the state of knowledge in the field. Scholars and experts in my field avoid these practices in their research.¹⁸ The reliability of researchers’ conclusions can be further undermined by failing to describe the methodology and procedures used to review documents in any detail, failing to specify a scientifically valid framework or theory to which the research methodology would be connected, failing to discuss or consider explanations that rival the narrative/conclusions, failing to discuss or consider limitations in making generalized conclusions based on the sample data relied on, and failing to discuss the potential effects of bias.
41. The allegations by plaintiffs fundamentally question what J&J knew, and when, about the alleged presence of asbestos in talc. This type of question can be addressed by a researcher trained in organization science, applying the tools and methods appropriate for this type of question.

1. Employing a Conceptual Framework Appropriate for the Research Question

42. Based on my training, experience, and understanding of the documentary evidence available, the research question here – what did J&J know, and when, about the presence

¹⁸ See, e.g., Miles, Matthew B. and A. Michael Huberman. *Qualitative Data Analysis*. 2nd ed., Sage Publications, Inc., 1994 (hereafter, “Miles and Huberman”), pp. 277-280 regarding “Standards for the Quality of Conclusions.” As Miles and Huberman discuss, it is important to acknowledge that “‘getting it all right’ is an unworkable aim” but that “some accounts are better than others.” Without prescribing “‘rules’ to be stiffly applied,” Miles and Huberman identify five issues that can be examined when judging the quality or reliability of qualitative work. These issues include: 1) Objectivity/Confirmability; 2) Reliability/Dependability/Auditability; 3) Internal Validity/Credibility/Authenticity; 4) External Validity/Transferability/Fittingness; and 5) Utilization/Application/Action Orientation. See Miles and Huberman, pp. 277-280.

of asbestos in talc – is the type of question best answered with a retrospective review of the available evidence arrayed against a framework designed to assess the contemporaneous incentives, motivations, and actions of an organization. For this purpose, researchers in my field often rely on a widely used and highly cited framework referred to as “sensemaking.”¹⁹ Sensemaking is an established framework for evaluating how new information enters an organization, how the organization interprets that information, and how the organization then chooses to act upon the information.²⁰ Simply put, sensemaking is the process by which organizations answer the following questions: “what’s going on here?” and “what do I do next?”²¹ Critically, sensemaking is a *social* process; knowledge and understanding emerge through the sharing of multiple perspectives, both from within and outside the organization.²² It is also an *ongoing* process; sensemaking in organizations involves making sense of changes that have

¹⁹ There are decades of research into sensemaking across a variety of contexts and situations, and there is general agreement that sensemaking is a critical capability in organizations. *See, e.g.,* Maitlis, Sally and Marlys Christianson, “Sensemaking in Organizations: Taking Stock and Moving Forward,” *The Academy of Management*, Vol. 8, No. 1, 2014 (hereafter, “Maitlis and Christianson”), pp. 58, 94 (“Sensemaking—the process through which individuals work to understand novel, unexpected, or confusing events—has become a critically important topic in the study of organizations. When organizational members encounter moments of ambiguity or uncertainty, they seek to clarify what is going on by extracting and interpreting cues from their environment, using these as the basis for a plausible account that provides order and “makes sense” of what has occurred, and through which they continue to enact the environment [...] a retrospective review of sensemaking that concludes sensemaking is “the heart of processes of change, learning and innovation in organizations.”). *See also, e.g.,* Sandberg, Jörgen and Haridimos Tsoukas, “Making Sense of the Sensemaking Perspective: Its Constituents, Limitations, and Opportunities for Further Development,” *Journal of Organizational Behavior*, Vol. 36, 2015, which reviews 147 articles that have applied a sensemaking framework within the context of an organizational study; Gioia, Dennis A. and Kumar Chittipeddi, “Sensemaking and Sensegiving in Strategic Change Initiation,” *Strategic Management Journal*, Vol. 12, 1991.

²⁰ *See, e.g.,* Weick, Karl E., “Sensemaking in Organizations,” *Foundations for Organizational Science*, 1995 (hereafter, “Weick (1995)”). *See also* Stern, Neill, Daryl McKee, and Gregory M. Rose, “Developing the Organization’s Sensemaking Capability: Precursor to an Adaptive Strategic Marketing Response,” *Industrial Marketing Management*, Vol. 36, No. 6, 2007 (hereafter, “Stern, McKee, and Rose (2007)”). Sensemaking is a concept and framework appropriately placed within the broader field of study referred to as “organizational learning.” The field of organizational learning describes these processes from a rich and diverse set of frameworks and perspectives. *See, e.g.,* Huber, George P., “Organizational Learning: The Contributing Processes and the Literatures,” *Organization Science*, Vol. 2, No. 1, February 1991; Weick, Karl E., “The Nontraditional Quality of Organizational Learning,” *Organization Science*, Vol. 2, No. 1, February 1991; Crossan, Mary M., et al, “An Organizational Learning Framework: From Intuition to Institution,” *Academy of Management Review*, Vol. 24, No. 3, July 1999; Vera, Dusya and Mary Crossan, “Strategic Leadership and Organizational Learning,” *Academy of Management Review*, Vol. 29, No. 2, 2004; Daft, Richard and Karl E. Weick, “Toward a Model of Organizations as Interpretation Systems,” *Academy of Management Review*, Vol. 9, No. 2, 1984.

²¹ Weick, Karl E., Kathleen M. Sutcliffe, and David Obstfeld, “Organizing and the Process of Sensemaking,” *Organization Science*, Vol. 16, No. 4, July-August 2005 (hereafter, “Weick, Sutcliffe, and Obstfeld (2005)”).

²² *See, e.g.,* Maitlis, Sally, “The Social Processes of Organizational Sensemaking,” *The Academy of Management Journal*, Vol. 48, No. 1, 2005. *See also, e.g.,* Stern, McKee, and Rose (2007).

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already occurred *and* have yet to occur.^{23, 24} I summarize the sensemaking process and its salient features below.

43. Typically, sensemaking activities are triggered by uncertainty, or “disruptive ambiguity.”²⁵ In order for an organization to make decisions, it first needs to make sense of the available information. Therefore, in an attempt to resolve this disruptive ambiguity, an organization will begin by collecting knowledge, both internally and externally.²⁶ Then, the organization will simultaneously interpret this new knowledge, act upon its interpretations, and test these interpretations and actions against the understanding of others.²⁷ This sensemaking process leads to a widely shared articulation, or “map,” of what is going on, what to pay attention to, and what to do next. Put differently, the “map” represents the internalized knowledge that an organization relies upon to make decisions, shares externally, and updates with new information over time. Importantly, the wide sharing, testing, and revising of the “map” continues even after the initial disruptive ambiguity is resolved, particularly when new information enters the environment.²⁸ Throughout this process, the organization will improve its own sensemaking capabilities to better respond to future uncertainties.²⁹ When studying organizations engaged in the process of sensemaking, I look for evidence that they adhered to these “best practices.”
44. To address the question of what J&J knew, and when, about the presence of asbestos in talc, I have relied on this highly cited “sensemaking” framework to conduct an organizational assessment of J&J, employing the analytic tools and methods used in the

²³ See Ancona, Deborah, “Chapter 1: Sensemaking,” *The Handbook for Teaching Leadership*, 2011 (hereafter, “Ancona (2011)”), p. 5 (“[S]ensemaking involves coming up with plausible understandings and meanings; testing them with others and via action; and then refining our understandings or abandoning them in favor of new ones that better explain a shifting reality.”).

²⁴ Sensemaking is simultaneously retrospective (backward-looking) and prospective (forward-looking). The prospective element of sensemaking involves agency, anticipation, and directing of future attention. Sensemaking is not something organizations achieve and put behind them, but rather is a capability in continuous use by individuals and, collectively, by organizations.

²⁵ See Sutcliffe, Kathleen M., “Sensemaking,” in M. Augier and D.J. Teece (Eds.), *The Palgrave Encyclopedia of Strategic Management*, 2014. See also Bogner, William C. and Pamela S. Barr, “Making Sense in Hypercompetitive Environments: A Cognitive Explanation for the Persistence of High Velocity Competition,” *Organization Science*, Vol. 11, No. 2, 2000; Weick, Sutcliffe, and Obstfeld (2005).

²⁶ See Weick, Sutcliffe, and Obstfeld (2005); Ancona (2011), p. 5.

²⁷ See Weick, Sutcliffe, and Obstfeld (2005); Ancona (2011), p. 5.

²⁸ See, e.g., Ancona, Deborah, et al., *Managing for the Future: Organizational Behavior and Processes*, 3rd Edition, 2009, p. M14-10.

²⁹ See Weick, Sutcliffe, and Obstfeld (2005); Ancona (2011), p. 5.

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field of organization science.³⁰ Specifically, I assessed whether J&J was engaged in these sensemaking “best practices,” whether J&J’s sensemaking activities were aligned with its stated priorities, including its commitment to the wellbeing of consumers, and whether J&J’s sensemaking informed its decision-making in order to promote and pursue those priorities. To do this, I conducted a holistic assessment, considering a wide variety of documents and data, in reaching my opinions. I further considered information regarding J&J’s incentives, motivations, and actions in the context of its stated priorities. My opinions take into consideration the following:

- 1) The evolving science and information available regarding asbestos and the health effects of exposure to asbestos and/or talc;
 - 2) Variation in knowledge, capability, and incentives related to identifying asbestos in talc among the industry, regulators, scientists, and the media;
 - 3) J&J’s resources and capabilities committed to product safety, and specifically with regards to the testing of its talc for the presence of asbestos; and
 - 4) J&J’s policies, procedures, internal documents, and employee interviews that articulate its organizational priorities and describe its organizational ethos.
45. An assessment of an organization’s sensemaking processes focuses on what was known, and when. In this way, a sensemaking perspective prevents hindsight bias that is inherent in many retrospective assessments of organizational behavior. Specifically, an organizational assessment employing a sensemaking framework does not impose judgments regarding what “should” have been known, but rather focuses on what was known, and what actions resulted from that knowledge, at that point in time.³¹ The organizational assessment described in this report focuses on the sensemaking processes that *actually* occurred within J&J, assessing these processes relative to the “best

³⁰ See, e.g., Sandberg, Jörgen and Haridimos Tsoukas, “Making Sense of the Sensemaking Perspective: Its Constituents, Limitations, and Opportunities for Further Development,” *Journal of Organizational Behavior*, Vol. 36, 2015, which reviews 147 articles that have applied a sensemaking framework within the context of an organizational study.

³¹ See, e.g., Dekker, Sidney, *The Field Guide to Understanding “Human Error,”* 3rd Edition, pp. 90-93. By putting information, actions, and understanding into context, and temporally into a continuous stream of sensemaking, researchers overcome preexisting or implicit assumptions about the ability of the organization to notice, understand, and act on any particular piece of information. See, e.g., Weick, Sutcliffe, and Obstfeld (2005), pp. 409-410. A sensemaking lens also prevents researchers from engaging in wishful thinking, or hypothesizing about other possible futures.

practices” in sensemaking described above, and interpreting J&J’s incentives, motivations, and actions in proper context.^{32, 33}

2. Employing a Robust and Replicable Qualitative Research Methodology

46. Studying sensemaking within a given context is a challenging exercise as its interactive, emergent, and evolving aspects can be difficult to observe and capture.³⁴ To understand how sensemaking is accomplished and what sensemaking helps to achieve, it is critical to analyze data that provide revealing descriptions of the sensemaking process as it unfolds over time.³⁵ It follows then that many of the established methods used to study sensemaking – such as case studies and textual analysis – draw upon rich qualitative data to illustrate the process of sensemaking.³⁶ Qualitative research is particularly appropriate for investigating complex processes as they unfold over time and is well-suited to using a sensemaking lens because it entails understanding the context of action from the perspective of the participants.³⁷
47. To conduct my assessment, I employed qualitative research methods to assess what J&J knew – and when – about the alleged presence of asbestos in its baby powder, what actions J&J took because of this knowledge, and the extent to which J&J’s actions were consistent with an organizational commitment to the wellbeing of consumers. Qualitative research methods were also necessary to understand more generally how J&J, industry regulators, scientists, and the press acquired new knowledge to inform their actions and develop new frameworks for understanding the potential health risks associated with cosmetic talc use.
48. My approach to qualitative research in this matter is based on my decades of research in my field, as well as the body of knowledge in my field related to qualitative research. In particular, the concepts and frameworks presented in Matthew B. Miles and A. Michael

³² When studying organizations, researchers look for evidence that organizations and leaders have engaged in these practices when new knowledge enters the environment and disrupts existing understandings. *See, e.g.,* Ancona, Deborah, et al., “In Praise of the Incomplete Leader,” *Harvard Business Review*, February 2007.

³³ When assessing individual facts, statements, or documents within the context of sensemaking, I was able to trace how and when J&J noticed information, and whether the process of noticing contributed to developing a new framework for understanding that guided J&J’s actions. *See, e.g.,* Weick (1995), p. 172.

³⁴ *See* Maitlis and Christianson, p. 105.

³⁵ *See* Maitlis and Christianson, p. 106.

³⁶ *See* Maitlis and Christianson, p. 106.

³⁷ *See* Blatt, Ruth et al. “A sensemaking lens on reliability.” *Journal of Organizational Behaviour*, Vol. 27, No. 7, 2006, p. 900.

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Huberman's *Qualitative Data Analysis* are widely cited and provide informative descriptions of various methods of qualitative research that I utilize.³⁸

49. In conducting my assessment, I have considered a significant volume of documents consisting of:

- 1) Materials produced in the J&J baby powder/talc product litigation matters;
- 2) Statements from J&J employees, including deposition testimony, trial testimony, and primary interviews;
- 3) Publicly available materials, including documents available on J&J's website and the websites of various regulatory agencies; and
- 4) Academic literature related to J&J, organizational behavior, and sensemaking.

50. Given the volume of documents in this matter, it is imperative that my qualitative analysis is grounded in explicit and systematic methods to design the qualitative research, collect data, and analyze data. Analyzing qualitative data can yield useful explanations, but the findings of any qualitative data analysis may be regarded as unreliable if the analysis is approached in an arbitrary fashion or if the analysis fails to account for common issues with qualitative data analysis. With the assistance of employees at Analysis Group, Inc. working under my direction, I used the methodology described below to review the documents available to me.

a. Qualitative Research Design

51. As mentioned above, the conclusions drawn from any qualitative data analysis may be invalidated if the analysis is approached arbitrarily. Therefore, I first considered the *design* of the qualitative research to be conducted in this matter before reviewing any of the documents.³⁹ The purpose of considering the design of the qualitative research is to

³⁸ Miles and Huberman.

³⁹ See Miles and Huberman, p. 16 ("[S]tudy design decisions can, in a real sense, be seen as analytic—a sort of *anticipatory data reduction*—because they constrain later analysis by ruling out certain variables and relationships and attending to others. Design decisions also permit and support later analysis; they prefigure your analytic moves. Some design decisions are mainly conceptual: the conceptual framework and research questions, sampling, case definition, instrumentation, and the nature of the data to be collected. Others..., though they appear in the guise of 'management' issues, are equally focusing and bounding: how data will be stored, managed, and processed; what computer software may be used to support the work; and which agreements are made with the people being studied.").

appropriately bound, focus, and organize the study given its idiosyncratic features and to allow for redesign as the study develops.⁴⁰

52. I initially contemplated how much structure should be imposed before conducting the qualitative research. “Tight” designs provide more concrete boundaries for the researcher while “loose” designs allow for a more emergent and inductive approach.⁴¹ and in the context of my assessment, I determined that a tighter qualitative research design was appropriate. This case was inherently defined by the allegations that J&J baby powder/talc products were contaminated with asbestos and that these allegedly contaminated J&J baby powder/talc products caused plaintiffs to develop cancer. Furthermore, the data collection was primarily defined by the documents in the ongoing J&J baby powder/talc product litigation matters. In addition to these documents, I reviewed deposition testimony, trial testimony, publicly available materials, and academic literature, and I also conducted interviews with J&J employees.
53. By virtue of plaintiffs’ claims and the availability of rich qualitative data, the direction of the qualitative research was more clearly defined with well-delineated constructs. In fact, my assessment necessitated a qualitative research design that was confirmatory – that is, the purpose of my qualitative analysis was to establish what J&J knew – and when – about the potential for asbestos in its baby powder and the potential association between cosmetic talc and cancer. Establishing these facts necessitated confirming more generally how J&J, industry regulators, scientists, and the press acquired new knowledge to inform their actions and develop new frameworks for understanding the potential health risks associated with cosmetic talc use.⁴²
54. Once I established that my assessment required a tighter qualitative research design, I sought to build a more nuanced conceptual framework to further focus and bound my

⁴⁰ See Miles and Huberman, p. 16 (“[T]hese issues must be dealt with uniquely in any particular study. They may be approached loosely or tightly; in either case, initial design decisions nearly always lead to redesign. Qualitative research designs are not copyable patterns or panaceas that eliminate the need for building, revising, and ‘choreographing’ your analytic work.”).

⁴¹ “Tight” designs provide more concrete boundaries for the researcher while “loose” designs allow for a more emergent and inductive approach. For example, tight research designs will often provide a preexisting conceptual framework, set of research questions, and predesigned devices for collecting data. Loose research designs allow for the conceptual frameworks and important research questions to emerge from the field in the course of study. See Miles and Huberman, pp. 16-17.

⁴² I note that while my assessment called for a qualitative research design that falls closer to the “tight” end of the spectrum, a tighter research design does not prevent redesigning or revising aspects of the qualitative research. For example, a tighter research design will often provide researchers with preexisting conceptual frameworks and research questions at the outset, but these conceptual frameworks and research questions can evolve or new frameworks and questions can be developed as the study progresses. Indeed, this iterative process to qualitative research is its own sensemaking process as the researcher studies sensemaking within a given context.

research and analysis. A more detailed conceptual framework helps to explain “the main things to be studied... and the presumed relationships among them,” which ultimately aids in generating hypotheses and theories.⁴³

55. Building out my conceptual framework started with categories, or intellectual “bins,” that incorporated the particulars of the research.⁴⁴ I developed an initial set of bins based on distinct time periods. Because my assessment aimed to understand sensemaking, documents that are temporally near each other were most important to review and assess as a group because it enabled a longitudinal view of how J&J (and others) built on previous understandings over time. Constructing bins temporally facilitated my own sensemaking of how various players, factors, and variables interacted and influenced one another, and how these relationships helped advance sensemaking regarding claims of asbestos contamination in baby powder/talc products and claims of an association between cosmetic talc and cancer. As the research progressed, the intellectual bins and resulting conceptual framework guiding the research were refined.⁴⁵
56. Next, I developed research questions based on assumed relationships established in the conceptual framework driving the analysis. Research questions build on the conceptual framework to focus and bound the study and operationalize the conceptual framework by making theoretical assumptions more explicit and prioritizing the topics or issues that the researcher wants to know first.⁴⁶ The temporal nature of the bins facilitated the identification of a logical chain of events, so research questions such as ‘Did J&J’s business decisions incorporate new scientific knowledge?’ and ‘Did J&J continue to test and update its understanding of the potential for asbestos contamination in its baby powder?’ were inherent in the conceptual framework guiding the research. I revised my research questions, added new research questions, and revised my conceptual framework

⁴³ See Miles and Huberman, p. 18.

⁴⁴ Miles and Huberman, p. 18 (“Theory building relies on a few general constructs that subsume a mountain of particulars... Bins come from theory and experience and (often) from the general objectives of the study envisioned.”).

⁴⁵ See Miles and Huberman, p. 22 (“Expect to do several iterations, right from the outset. There are probably as many ways of representing the main variables as there are variables to represent, but some—typically later cuts—are more elegant and parsimonious than others.”).

⁴⁶ See Miles and Huberman, p. 22 (“What do these questions do for me? First, they make my theoretical assumptions more explicit. Second, they tell me what I want to know most or first; I will start channeling my energy in those directions. My collection of data will be more focused and limited... Finally, the rough boundaries of my analysis have been set, at least provisionally. If I ask, How do policymaker actions affect adopter behavior? I will be looking at data on adopter behaviors, policymaker actions, and their influences on each other, not at what else affects adopter behaviors. The research questions begin to operationalize the conceptual framework.”).

as my review of the documents progressed, consistent with contemporary theory on qualitative data analysis.⁴⁷

57. Finally, I defined the case and bound the territory.⁴⁸ For my assessment, the case can be defined as J&J (focus) in the context of the disruptive ambiguity caused by claims of potential asbestos contamination in its baby powder/talc products, claims of an association between cosmetic talc and cancer, and its interactions with the industry, regulators, scientists, and the press before, during, and after these claims (boundary). Furthermore, the temporal bins that comprise my conceptual framework can be considered subcases that collectively build to my overall opinions regarding J&J engaging in sensemaking before, during, and after the claims pertaining to the potential for asbestos in its baby powder and the potential association between cosmetic talc and cancer.⁴⁹

b. Data Collection and Management

58. As mentioned above, a robust assessment typically incorporates many types of evidence. I had access to multiple sources of qualitative data while also conducting primary research. As part of my assessment, I considered materials produced in J&J baby powder/talc product litigation matters, deposition testimony, trial testimony, statements

⁴⁷ See Miles and Huberman, p. 23 (“Research questions and conceptual frameworks—either implicit/emerging or prespecified—affect each other... The formulation of research questions may precede or follow the development of a conceptual framework... Research questions may be general or particular, descriptive or explanatory. They may be formulated at the outset or later on, and may be refined or reformulated in the course of fieldwork.”).

⁴⁸ Thoughtfully considering the design of qualitative research should ultimately clarify the case for the researcher (i.e., what the case is and where it ends). See Miles and Huberman, p. 25 (“Qualitative researchers often struggle with the questions of ‘what my case is’ and ‘where my case leaves off.’ Abstractly, we can define a *case* as a phenomenon of some sort occurring in a bounded context. The case is, in effect, your unit of analysis. Studies may be of just one case or of several.”). A case can be visualized as a central focus enclosed by a boundary that delineates what will and will not be studied in the case. See Miles and Huberman, pp. 25-26 (“There is a focus, or ‘heart,’ of the study, and a somewhat intermediate boundary defines the edge of the case: what will not be studied... Sometimes the ‘phenomenon’ may be an *individual* in a defined context: A patient undergoing cardiovascular bypass surgery, before, during, and 6 months after surgery, in the context of his or her family and the hospital setting... Note that the ‘heart’ here is the patient. The boundary defines family and hospital as the context. The researchers will not, for example, interview the patient’s colleagues at work or visit the restaurants where he or she dines. The bounding is also by time: No information will be gathered later than 6 months after hospitalization.”).

⁴⁹ Cases can be defined in many ways, including by the nature and size of the “social unit” (e.g., individual, role, small group, organization, community, nation), spatially, temporally, by episode or encounter, by event, by period of time, or by process. See Miles and Huberman, p. 26. Additionally, qualitative research does not need to be limited to a single case; a case may include subcases within it and researchers may study multiple cases to examine rivaling theories and achieve a deeper understanding of processes, outcomes, and causality. See Miles and Huberman, p. 26 (“So far we have discussed the ‘case’ as if it were monolithic. In fact... cases may have subcases ‘embedded’ within them... [M]ultiple cases offer the researcher an even deeper understanding of processes and outcomes of cases, the chance to test (not just develop) hypotheses, and a good picture of locally grounded causality.”).

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from J&J employees, publicly available materials, and academic literature related to J&J and sensemaking.

59. At the start of my research, in response to my request for an initial data sample relevant to my assessment, counsel for J&J provided approximately 600 documents to me and my team. Consistent with the iterative nature of qualitative research, I then requested and received access to J&J's full global production record in the J&J baby powder/talc product litigation matters, which included more than 500,000 documents produced by J&J.⁵⁰ With access to this production database, I asked my team to perform queries designed to identify additional documents related to the initial documents already reviewed and binned. In addition, I received J&J's Responses to Plaintiff's LAOSD (Los Angeles, Orange, and San Diego Counties) Interrogatories and corresponding "Document Production" in the *Gutierrez* matter.⁵¹ I reviewed documents that were categorized under certain "Topics" provided in the "Document Production" that were relevant to my assessment. Outside of production materials, I continued requesting and reviewing additional documentation. For example, I asked for and reviewed deposition and trial testimony from J&J personnel as they became available, and I reviewed publicly available documents such as documents available on J&J's website, including J&J's Credo and certain organizational policies and procedures, and the websites of various regulatory agencies. I discuss in more detail below my iterative process of collecting, managing, and analyzing the data.

(1) Production Materials

60. The record in the J&J baby powder/talc product litigation matters consists of hundreds of thousands of documents, rendering a complete manual review of all the documents impossible. Consistent with contemporaneous theory on qualitative data analysis, I relied on purposive sampling of the documents through a theory-based sampling strategy.⁵²

⁵⁰ In October 2019, I received access to more than 480,000 documents from J&J Defendants' production. In June 2021, I received an additional 80,000 documents supplementing J&J Defendants' production since December 2019.

⁵¹ Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Responses to Plaintiff's LAOSD Standard Interrogatories, *Maricela Gutierrez v. Johnson and Johnson et al.*, Case No. 19STCV02585, Superior Court of the State of California for the County of Los Angeles, September 18, 2019.

⁵² See Miles and Huberman, p. 27 ("Sampling is crucial for later analysis. As much as you might want to, you cannot study everyone everywhere doing everything... Qualitative samples tend to be *purposive*, rather than random... That tendency is partly because the initial definition of the universe is more limited (e.g., arrest-making in an urban precinct), and partly because social processes have a logic and a coherence that random sampling can reduce to uninterpretable sawdust. Furthermore, with small numbers of cases, random sampling can deal you a decidedly biased hand... Qualitative sampling is often decidedly *theory-driven*, either 'up front' or progressively, as in a grounded theory mode.").

61. For an initial sample, I requested that counsel for J&J conduct an exhaustive search of the production record for documents that would be relevant to my assessment, such as (i) materials related to industry, regulatory, scientific, and media perspectives on whether cosmetic talc contains asbestos, and how these perspectives changed over time, (ii) materials that inform a general understanding of J&J's orientation toward health and safety, and ordinary course of business documents regarding the health/safety of J&J baby powder, and (iii) materials that inform an understanding of how J&J was organized to respond to potential health/safety issues related to its baby powder/talc products, its capabilities to do so, and the associated expenditures. This sampling was consistent with the focus and boundaries established in the qualitative research design described above, and the sample was arrayed against my conceptual framework of sensemaking during the manual review of the documents to allow for scrutiny and revision of the study's constructs.⁵³
62. Much like other aspects of qualitative data analysis, the sampling process was also iterative.⁵⁴ Following a manual review of the sample documents, I requested additional documents from counsel to fill gaps in knowledge and to confirm or disconfirm patterns and themes identified in the initial sample.⁵⁵ I also had access to a database of J&J's full production record and performed queries designed to identify additional documents related to the documents already reviewed and binned. To the extent that additional documents were identified, those documents were reviewed. To the extent that these additional documents were found to contain incremental information, they were binned with the antecedent document and included in my report as appropriate.⁵⁶

⁵³ See Miles and Huberman, p. 27 ("Sampling qualitative research involves two actions that sometimes pull in different directions. First, you need to set *boundaries*: to define aspects of your case(s) that you can study within the limits of your time and means, that connect directly to your research questions, and that probably will include examples of what you want to study. Second, at the same time, you need to create a *frame* to help you uncover, confirm, or qualify the basic processes or constructs that undergird your study.").

⁵⁴ See Miles and Huberman, p. 27 ("Samples in qualitative studies are usually not wholly prespecified, but can evolve once fieldwork begins. Initial choices of informants lead you to similar and different ones; observing one class of events invites comparison with another; and understanding one key relationship in the setting reveals facets to be studied in others. This is conceptually-driven sequential sampling.").

⁵⁵ See Miles and Huberman, p. 29 ("[W]ithin-case sampling has an *iterative* or 'rolling' quality, working in progressive 'waves' as the study progresses... At each step of along the evidential trail, we are making sampling decisions to clarify the main patterns, see contrasts, identify exceptions or discrepant instances, and uncover negative instances—where the pattern does not hold. Our analytic conclusions depend deeply on the within-case sampling choices we made").

⁵⁶ See Miles and Huberman, p. 263 ("We also draw on this literature as we discuss tactics for testing/confirming findings. The language of 'confirming' and 'verifying' is bolder than what we can usually achieve. But the intent is still there: How can we increase our—and our readers'—confidence in what we've found? ... [T]he answer lies in linking three levels of understanding: the meanings and interpretations of our informants, our own interpretations of those meanings, and our confirmatory, theory-connected operations.").

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63. To supplement my review of J&J's full production database, I also reviewed documents that were categorized under certain "Topics" provided in the "Document Production" that were relevant to my assessment.⁵⁷ These relevant "Topics" include "Discussion of Health and/or Safety," "Regulatory and Government Communications," and "Corporate History/Structure," among others. I leveraged these existing bins in two ways.⁵⁸ First, I identified which documents in the relevant "Topics" were incremental to the documents I had already reviewed. I reviewed the incremental documents, binned them according to my themes, and included them in my report as appropriate. Second, I identified the extent to which the documents I had previously binned were present in this production, and which "Topic(s)" had been assigned to them. This process served as an independent check on the binning I conducted in my own review.

(2) Documents Outside Production

64. Throughout the course of my assessment, I also considered documents outside of production. I considered statements from J&J employees that were obtained through deposition testimony, trial testimony, and primary research. These accounts and testimonies were useful data sources to confirm or disconfirm facts and to validate interpretations, patterns, and themes that emerged from the manual review of the materials. I also considered publicly available materials obtained through independent research, and relevant academic literature.
65. In conducting primary research, I interviewed Dr. John Hopkins, a former products safety officer and toxicologist for J&J from 1976 to 2000. This interview was useful to understand Dr. Hopkins' perception of J&J's commitment to the wellbeing of consumers, as well as his perspective on J&J's sensemaking related to the allegations of asbestos

⁵⁷ See Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Responses to Plaintiff's LAOSD Standard Interrogatories, *Maricela Gutierrez v. Johnson and Johnson et al.*, Case No. 19STCV02585, Superior Court of the State of California for the County of Los Angeles, September 18, 2019, pp. 3-4 ("Defendants have made additional reasonable and good-faith efforts to identify documents in their Document Production that relate in a reasonably direct manner to certain topics ("Topics"). In developing the Topics, Defendants have taken into account the claims and defenses in talc personal injury litigation, as well as specific discovery requests Defendants have received. These Topics are identified below and the documents relating to such Topics will be identified in a spreadsheet that accompanies the Document Production. By providing such information to Plaintiff, Defendants are not stating that every document in the Document Production that may relate in some way to a Topic has been identified on the spreadsheet, but rather that Defendants have taken reasonable steps to identify such documents.")

⁵⁸ *Ibid*, p. 4 ("The Topics are as follows: 1. Talc Sources (Mines/Mills/Suppliers); 2. Manufacturing; 3. Testing; 4. Formulas/Product Specifications; 5. Packaging Specifications/Labelling; 6. Advertisements; 7. Marketing; 8. Sales/Distribution; 9. Studies/Medical Literature; 10. Adverse Events/Complaints/Workers' Comp Files; 11. Warnings; 12. Discussion of Health and/or Safety; 13. Regulatory and Government Communications; 14. Trade Associations; 15. Cornstarch and Non-Talc Powder Formulations; 16. Corporate History/Structure (Annual Reports, 10-Ks, Histories, Corporate Structure Documents)."). Documents produced and provided to me after September 2019 were categorized under similar topics.

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contamination in J&J baby powder/talc products. Additionally, I interviewed Dr. Susan Nicholson, the former Vice President of Women's Health in J&J's Office of the Chief Medical Officer who held other leadership positions at J&J related to consumer safety. These positions include Pharmacovigilance Strategy Leader in Janssen Pharmaceuticals' Scientific Affairs department, Vice President of Safety Operations and Compliance in J&J's Medical Devices and Diagnostics department, and Vice President of Safety Surveillance and Risk Management in J&J's Office of Consumer Medical Safety.⁵⁹ Dr. Nicholson's account was particularly important to contextualize J&J's medical departments and groups relative to J&J's organization as a whole.

66. I supplemented my primary research and analysis of case-specific documents and testimony by conducting independent research based on publicly available materials, such as the "Facts About Talc," "Toxic Docs," and FDA websites. I also conducted an academic literature review. Specifically, I reviewed academic literature in my field related to J&J and sensemaking, as well as my own academic work pertaining to sensemaking. I examined academic literature that is consistent with, inconsistent with, and neutral to my hypotheses.

c. Data Analysis

67. Under my direction, my team and I tracked which documents were received, and everything received was queried and/or reviewed. As documents were reviewed, they were assigned to bins in my conceptual framework that correspond to the structure of my report. **Appendix C** contains a full list of the documents considered.
68. Consistent with the contemporaneous theory of qualitative research, I cycled back and forth between data collection and analysis.⁶⁰ Using the initial sample of data responsive to my request, and with the assistance of others working under my direction, I conducted a manual review of these documents. Each document was reviewed individually by two researchers. The two researchers then compared their interpretation, characterization, and binning of the documents. Disparate views regarding this interpretation, characterization,

⁵⁹ See Undated – DX D25.

⁶⁰ A common misconception in qualitative data analysis is that the researcher must collect all the data before performing any analysis. This approach is flawed because it prevents the researcher from collecting new data to fill in gaps in knowledge or investigating rivaling theories throughout the course of the study. See Miles and Huberman, p. 50 ("Some qualitative researchers put primary energy into data collection for weeks, months, or even years and then retire from the field to 'work over their notes.' We believe this is a mistake. It rules out the possibility of collecting new data to fill in gaps, or to test new hypotheses that emerge during analysis. It discourages the formulation of 'rival hypotheses' that question a field-worker's routine assumptions and biases. And it makes analysis into a giant, sometimes overwhelming, task that demotivates the researcher and reduces the quality of the work produced.").

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and binning of the documents were reconciled through discussions between the two researchers and myself.⁶¹

69. While this analysis of the initial data sample yielded themes, patterns, and constructs in the data, it also helped identify gaps in understanding. Identifying these gaps in knowledge was helpful to target additional data, which could then be used to refine the initial bins comprising the conceptual framework and validate or invalidate themes that emerged from the first wave of analysis.⁶²
70. I had access to and considered many other materials, which I reviewed to fill in any gaps or to supplement my knowledge as new information became available. I queried the production database, identified documents from the “Topics” spreadsheet that were relevant to my assessment, and researched new topics as information became available. For example, when I received the J&J Defendants’ production supplementation in June 2021, I performed queries related to more recent events, such as J&J’s voluntary recall of Lot ##22318RB in 2019 and J&J’s interactions with Health Canada in 2020.
71. Supplementing my review of the production documents, I also reviewed trial and deposition testimony as well as other non-production documents, including documents available on J&J and regulatory agencies’ website. For example, I reviewed materials from the *Ingham, et al. v. Johnson & Johnson, et al.* matter as they became available, including the deposition testimony of J&J’s then-Chief Medical Officer, Dr. Joanne Waldstreicher; trial testimony of Dr. Nicholson; and opening and closing statements from counsel for plaintiffs and for J&J. All of these materials were analyzed consistent with the description above of the analysis employed for the production documents.
72. Overall, the qualitative research method I employed serves to achieve an analytic progression from describing to explaining, or drawing conclusions from, the data. I first started with raw data and arranged these data into bins in order to summarize and organize the data. I then leveraged these bins to identify themes and patterns in the data, as well as gaps in the data that required clarification. Finally, I cycled through multiple rounds of data collection and analysis to validate emergent themes and patterns, and new information relevant to my research. My overall opinions regarding J&J engaging in sensemaking before, during, and after the claims pertaining to its baby powder/talc

⁶¹ This methodology is consistent with “check-coding.” See Miles and Huberman, p. 64 (“*Check-coding*. Definitions become sharper when two researchers code the same data set and discuss their initial difficulties. A disagreement shows that a definition has to be expanded or otherwise amended... Check-coding not only aids definitional clarity but also is a good reliability check.”).

⁶² See Miles and Huberman, p. 71 (“Finally, pattern codes get checked out in the next wave of data collection. This is largely an inferential process. The analyst tries out the theme..., engages in if-then tactics..., or checks out a rival explanation.”).

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products are informed by this rigorous and iterative research process, conducted over many years, and incorporating thousands of documents.⁶³

C. Plaintiffs' Opinions Are Based on an Incomplete and Biased Review of the Documentary Evidence

73. In the remainder of this report, I summarize the results of my organizational assessment of J&J, which I conducted over several years and which encompassed the review of thousands of documents relevant to the research question. My assessment is based on this documentary evidence, is rooted in an established research methodology for reviewing this documentary evidence, and uses a highly cited conceptual framework to address the question of what J&J knew, and when, about the presence of asbestos in talc. Contrary to the plaintiffs' causal narrative, it is my professional opinion that J&J actively pursued knowledge regarding the safety of its baby powder, consistent with its "Credo" and with behaviors I would expect to see in an organization that prioritizes consumer wellbeing.⁶⁴

1. Johnson & Johnson Has a Long History of Efforts to Minimize Impurities in Cosmetic Talc, Consistent with Contemporaneous Scientific Knowledge

74. The actions taken by J&J over many decades are consistent with a commitment to minimizing impurities in J&J's talc. These efforts included a commitment of resources to monitor, and respond to, potential safety issues related to the use of its consumer talc products. These efforts also included a commitment of resources to identifying high quality talc deposits from which to source its talc and a set of procedures to process and test the talc for impurities during production.
75. These actions, taken long before the current litigation, are consistent with an organization engaged in the sensemaking process. J&J devoted time, energy, and resources to seeking knowledge from the external environment and adapting its framework of knowledge regarding talc safety. This continuous "mapping" process enabled J&J to frequently test and revise its understanding of talc safety, make decisions to minimize impurities in its

⁶³ See Miles and Huberman, p. 91 ("The progression is a sort of 'ladder of abstraction'... You begin with a text, trying out coding categories on it, then moving to identify themes and trends, and then to testing hunches and findings, aiming first to delineate the 'deep structure' and then to integrate the data into an explanatory framework... Naturally there is no clear or clean boundary between describing and explaining; the researcher typically moves through a series of analysis episodes that condense more and more data into a more and more coherent understanding of what, how, and why.").

⁶⁴ J&J's Credo states that J&J believes its "first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services." See "Our Credo," *Johnson & Johnson*, available at <https://www.jnj.com/credo/>. See also Appendix E for a more detailed discussion of J&J's Credo and organizational policies and procedures.

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talc based on new knowledge, and bring an informed perspective to discussions with external stakeholders.⁶⁵

a. Early Efforts and Actions Taken by Johnson & Johnson

76. In 1893, J&J first marketed what would become Johnson's Baby Powder as a "Baby and Toilet Powder."⁶⁶ Johnson's Baby Powder is typically known as a cosmetic product with various applications, such as cooling and drying skin, soothing irritated skin, and as a deodorant.⁶⁷ However, studies have also found talc to be clinically useful for applications such as controlling skin irritation from papular urticaria (*i.e.*, hives) and maintaining dryness while treating certain fungal infections.⁶⁸ Early on, J&J developed significant expertise in cosmetic talc and became an industry leader on the subject.⁶⁹ Unlike other companies, it developed its own stringent specifications for talc that suppliers needed to meet.⁷⁰ J&J focused on minimizing non-talc trace minerals in its talc, including foreign matter and "acicular" particles.⁷¹
77. J&J stayed abreast of the literature on talc and other minerals and acknowledged when scientific questions were raised about the safety of the product. In the context of sensemaking, this effort to monitor the external environment was important for J&J to validate and/or refine its "map" based on the scientific knowledge available at the time. For example, in 1966, an article in the *American Journal of Diseases of Children* described a case treating a child's "massive talc aspiration" following a can being tipped over and covering the child's airway with talc.⁷² J&J engaged a broad team to initiate work to understand the phenomenon, obtain data, and develop mechanisms to reduce the hazard.⁷³ The company redesigned the packaging for Johnson's Baby Powder to include a "child resistant closure"⁷⁴ and would later add a warning to keep the bottle away from children.⁷⁵
78. Likewise, an early safety focus for J&J was on minimizing skin irritation in its historical baby powder formulas. In the 1950s and '60s, it performed skin irritation studies on both

⁶⁵ See *supra* Section IV.B for a description of the "mapping" of knowledge and understandings in sensemaking.

⁶⁶ Undated – JNJ 000290692 at 2.

⁶⁷ See JNJ 000236121; 1973 – JNJ TALC000633988.

⁶⁸ See JNJ 000236121; 1973 – JNJ TALC000633988.

⁶⁹ See 1965.10.07 – JNJ 000868191 at 9.

⁷⁰ See, e.g., 1949.05.20 – JNJ TALC000026016; 1965.10.07 – JNJ 000868191.

⁷¹ 1955.02.22 – DX7000.

⁷² 1966.06 – JNJ 000235852; see also 1966.06.17 – JNJ 000235850; 1966.06.15 – JNJ 000235851.

⁷³ See 1966.06.17 – JNJ 000235850.

⁷⁴ 1976.09.08 – JNJ 000244920.

⁷⁵ See 1985.07.09 – JNJ 000278033.

its talc and starch-based powders.⁷⁶ J&J concluded that its formulas were not likely to produce skin irritation.⁷⁷

79. In 1968, J&J investigated new methods for sterilizing talc following concerns of bacterial contamination prior to bulk storage.⁷⁸ Originally, while some J&J employees felt that “steam sterilization of bulk talc was an impossibility,” the company mounted an international research effort to run pilot experiments and was able to demonstrate that steam sterilization was “a feasible commercial sterilizing technique.”⁷⁹ Those efforts led to the development of a sterile Vermont talc that could be used in Johnson’s Baby Powder.⁸⁰
80. In April 1969, Bill Ashton – a mineralogist and research scientist within J&J with extensive knowledge of talc⁸¹ – asked for a medical opinion on the safety of tremolite.⁸² A few months prior, in November 1968, Bill Ashton called attention to the fact that there was increased scrutiny regarding asbestos and that this could lead to “serious misunderstandings” about talc.⁸³ Thus far, J&J had set out to minimize the presence of this mineral in its talc products when potential new source mines for J&J were suspected of containing that mineral.⁸⁴ Dr. Thompson, the Medical Director of the Baby Products Company, replied a week later, saying that J&J had monitored the literature for years for any health hazards related to talc inhalation and could identify no information in support of concerns over tremolite.⁸⁵ He noted having reviewed literature on pneumoconiosis among talc workers in the occupational setting as well.⁸⁶ Nevertheless, consistent with

⁷⁶ See 1959.09.01 – JNJ 000301482 at 497 (“Dr. T.M. Thompson had the following formulae tested for irritation by Dr. Harvey Blank of the University of Miami....All of the baby powders listed... failed to produce any burning on application to the skin.”); 1963.11.19 – JNJTALC000088537 (“It may thus be concluded that the samples as supplied would not be productive of primary irritation on normal skin.”); 1964.11.04 – JNJ 000265550 (comparing the effects of JBP with and without cornstarch on the skin and finding “neither of the powders tested is capable of producing primary irritation on normal skin”).

⁷⁷ See 1963.11.19 – JNJTALC000088537 (“It may thus be concluded that the samples as supplied would not be productive of primary irritation on normal skin.”).

⁷⁸ See 1968.02.14 – JNJ 000236627; see also 1968.04.16 – JNJ 000236614.

⁷⁹ 1971.12.01 – JNJ 000267392 at 7395.

⁸⁰ See 1971.12.01 – JNJ 000267392.

⁸¹ See 1983 – JNJ 000087974; June 4, 2020 Interview of Dr. John Hopkins; “Johnson Medal Awardees,” *Johnson & Johnson*, available at <https://www.jnj.com/sites/default/files/pdf/johnson-medal-winners.pdf> (Bill Ashton was awarded the Johnson Medal in 1965 for his work developing beneficiated talc.).

⁸² See 1969.04.09 – DX7724. See also **Figure 1** for a discussion of the different classifications of asbestiform and non-asbestiform minerals, including tremolite.

⁸³ See 1968.11.01 – JNJNL61_000001532.

⁸⁴ See 1969.04.09 – DX7724.

⁸⁵ See 1969.04.15 – JNJ 000087991.

⁸⁶ See 1969.04.15 – JNJ 000087991; see also Kleinfeld, M., et al., “Talc Pneumoconiosis,” *Archives of Industrial Health* Vol. 12 (1955).

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J&J's approach of minimizing impurities, and despite a lack of evidence that it was harmful, Dr. Thompson recommended limiting tremolite to the extent possible until further animal studies could be conducted.⁸⁷

b. Early Talc Sources and Quality Control

81. For nearly 50 years, J&J used a single mine in Italy as the source for its U.S. talc. The process of identifying, testing, and confirming that a domestic talc source could replace this source, and meet J&J's quality standards, took decades, as I describe below. This process, when seen through a sensemaking lens, confirms that J&J employed best practices in sensemaking and developed sensemaking capabilities that would underpin future actions and decisions regarding the quality and safety of its talc.
82. From 1926 through 1973, and for a brief period beginning in 1980, J&J sourced the cosmetic talc for Johnson's Baby Powder from the Fontana mine in the Val Chisone valley of Italy.⁸⁸ It gradually reduced the proportion of Italian talc in Johnson's Baby Powder between 1965 and 1967.⁸⁹ It began using talc from Windsor, Vermont in Shower to Shower from its introduction in 1967 until it reverted to Italian talc by the early 1970s after working on combining that product's fragrance with the Vermont talc.⁹⁰ Italian talc had to meet a number of requirements in J&J's specifications, including that it be free of "acicular" or "needle-like" particles.⁹¹ Additionally, the mine employed a multi-step sorting and milling process to provide J&J with an "excellent" and "high-grade" product.⁹²
83. In the years following the end of World War II, J&J began looking for "a domestic source of talc of equivalent quality for use in their baby powder" in light of the "possibility of economic and/or political instability in Italy."⁹³ In 1955, J&J contracted with the Battelle Memorial Institute ("Battelle") to begin the search for a suitable domestic talc source.⁹⁴ This years-long project involved, among other steps, the evaluation of talc deposits located all over the United States as well as the manual selection and evaluation of representative talc samples.⁹⁵ This process led J&J's Research

⁸⁷ See 1969.04.15 – JNJ 000087991.

⁸⁸ See **Figure 2A**. Note there was also a supply disruption during World War II, which required the company to find a temporary alternative source from California.

⁸⁹ See 1966.01.11 – JNJ 000235890 (noting Italian and Domestic (Vermont) talc were being blended on a 50-50 basis in 1966).

⁹⁰ Compare 1968.06.30 – JNJ 000085878 with 1972.10.17 – DX8372. See also JNJ 000351711.

⁹¹ 1955.02.22 – DX7000.

⁹² 1959.02.17 – JNJ 000088048.

⁹³ 1956.02.29 – DX8360 at 6.

⁹⁴ See 1956.02.29 – DX8360 at 6-7. See also **Figures 2A and 2B**.

⁹⁵ See 1956.02.29 – DX8360 at 7-8.

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Department to narrow its options down to the Hammondsville, Vermont talc mine, which was determined to be superior to other talcs,⁹⁶ including J&J's Italian talc.⁹⁷ By 1964, J&J had decided on Hammondsville, Vermont as its domestic talc source.^{98, 99} As with its Italian talc, J&J imposed quality requirements for this new talc source – including testing for the presence of amphiboles.¹⁰⁰ It also invested time and resources in developing the most advanced technology to beneficiate high-quality talc.¹⁰¹

84. J&J's search for a domestic talc source is an example of J&J committing organizational resources to sensemaking - that is, it sought out new information regarding potential talc sources, and made decisions based on a commitment to sourcing high-quality talc. This commitment of resources further developed J&J's sensemaking capabilities. These capabilities are critical to future sensemaking efforts and more generally, to support change, learning and innovation in organizations.¹⁰² These capabilities and perspectives were the foundation from which J&J engaged with and responded to early concerns regarding asbestos exposure, described below.

c. Early Concerns Regarding Asbestos Exposure

85. The record of scientific research and regulatory investigations indicates that early concerns regarding asbestos exposure emerged in the mid-1960s. As it had done with concerns regarding other potential impurities in talc, J&J followed this research and engaged in discussions with the scientific community and regulators. These discussions also informed J&J's sensemaking process and its efforts to create a "map" of the issues.

⁹⁶ 1961.06.06 – JNJ TALC000129140; *see also* 1962.01.25 – WTALC00001591 at 593.

⁹⁷ 1963.05.27 – JNJ 000087425; *see also* 1979 – DX8079 at 1 (Harvard School of Public Health environmental study of Vermont talc mines and mills noting that "studies dating from the early 1900's [had] shown that the Vermont talc deposits contain no asbestos and little quartz.").

⁹⁸ *See* 1964.04.21 – JNJ 000235105. *See also* **Figure 2B**.

⁹⁹ Shortly after selecting Hammondsville as its U.S. talc source, J&J began looking for a backup source to that deposit. *See* 1969.04.10 – JNJ 000089440; *see also* 1972.01.27 – DX7723. J&J used the experience and expertise gained from its search for a domestic deposit to evaluate and ultimately rule out each of the alternative deposits it investigated due to their inability to meet its quality requirements. *See, e.g.*, 1970.08.24 – JNJ TALC000070222; 1972.01.27 – DX7723 at 1 ("The last phases of the Grantham study coincided with the recent talc/asbestos [controversy]. That has a direct bearing on the appraisal of any new talc finding since we have to give high assurance of freedom of any mineral which might be considered to be an [asbestiform].").

¹⁰⁰ *See* 1962 – DX7988 at 15 (associate minerals, including amphiboles, "are to be less than 1.0% by count"); 1964.04.21 – JNJ 000235105 at 105 (talc shall be platelet, no "acicular" crystals). *See also* **Figure 1** for a discussion of the different classifications of amphiboles.

¹⁰¹ *See* 1973.04.20 – DX8265. *See also* 1962 – DX7988; 1965.10.07 – JNJ 000868191; 1969.04.24 – JNJ 000089431.

¹⁰² *See supra* **Section IV.B.1** for additional discussion of the importance of sensemaking capabilities in organizations.

86. In 1964, Dr. Irving Selikoff of Mount Sinai Medical Center – a leader in raising public health concerns about asbestos-related disease – published a paper on the increased risk of lung cancer and mesothelioma for insulation workers. Following the significant publicity brought by the paper and the New York Academy of Sciences International Conference on asbestos,¹⁰³ the United States enacted the Occupational Safety and Health Act of 1970 and established the administrative agency by the same name (“OSHA”), as well as the National Institute for Occupational Safety and Health (“NIOSH”).¹⁰⁴
87. At this point, in 1971, as part of its “‘start-up’ authority” to quickly address the issue of asbestos exposure, OSHA “published a list of PELs [permissible exposure limits] for general industry for many toxic substances including asbestos” based on measurements taken by the American Conference of Governmental Industrial Hygienists (“ACGIH”) a few years earlier.¹⁰⁵ NIOSH had also initiated numerous studies into the effects of asbestos exposure. J&J was aware of and followed this asbestos research as it developed.¹⁰⁶
88. Regulatory focus in the United States was not on consumer products, but on occupational exposure to asbestos in asbestos-using industries.¹⁰⁷ Nevertheless, scientists¹⁰⁸ and authorities¹⁰⁹ were coming to a shared understanding that the “asbestos” minerals of

¹⁰³ See Joseph Hooper, “The Asbestos Mess,” *The New York Times*, November 25, 1990, available at <https://www.nytimes.com/1990/11/25/magazine/the-asbestos-mess.html>.

¹⁰⁴ See Martonik, John, et al., “The History of OSHA’s Asbestos Rulemakings and Some Distinctive Approaches that They Introduced for Regulating Occupational Exposure to Toxic Substances,” *AIHAJ*, Vol. 62, No. 2 (2001). See also “Summary of the Occupational Safety and Health Act,” *Environmental Protection Agency*, available at <https://www.epa.gov/laws-regulations/summary-occupational-safety-and-health-act>; “About NIOSH,” *Centers for Disease Control and Prevention*, available at <https://www.cdc.gov/niosh/about/default.html>.

¹⁰⁵ See Martonik, John, et al., “The History of OSHA’s Asbestos Rulemakings and Some Distinctive Approaches that They Introduced for Regulating Occupational Exposure to Toxic Substances,” *AIHAJ*, Vol. 62, No. 2 (2001), at 209. See also “Summary of the Occupational Safety and Health Act,” *Environmental Protection Agency*, available at <https://www.epa.gov/laws-regulations/summary-occupational-safety-and-health-act>; “About NIOSH,” *Centers for Disease Control and Prevention*, available at <https://www.cdc.gov/niosh/about/default.html>.

¹⁰⁶ See 1971 – JNJTALC000445771; 1971.10.05 – JNJTALC000445773; 1971.09.29 – JNJTALC000445774; 1972.04.11 – JNJ 000328233.

¹⁰⁷ See Campbell, William, et al., “Selected Silicate Minerals and Their Asbestiform Varieties,” *U.S. Bureau of Mines Information Circular 8751* at 31 (1977).

¹⁰⁸ See, e.g., 1972 – JNJTALC001243499 at 500 (Newhouse et al., “A study of the mortality of female asbestos workers,” *British Journal of Industrial Medicine*, Vol. 29, 134-141 (1972)); 1979 – DX9052 at 4; 1980 – DX9267 at 9; 1984 – JNJ 000224493; 1983.09.29 – DX7183 (Letter from Dr. Malcom Ross, USGS, to William Ashton, Johnson & Johnson).

¹⁰⁹ See JNJTALC000288487 at 8518 - 8520 (Committee on Hygiene Standards of the British Occupational Hygiene Society, “Hygiene Standards for Chrysotile Asbestos Dust,” *The Annals of Occupational Hygiene*,

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concern were the asbestiform varieties of the commercially used minerals chrysotile, crocidolite, and amosite.¹¹⁰ When the FDA first discussed concerns over the trace asbestos minerals (tremolite, anthophyllite, and actinolite)¹¹¹ with scientists and the industry, the group collectively recognized the importance of distinguishing between the asbestiform and massive varieties of those minerals.¹¹² J&J was aware of and often participated in these discussions.¹¹³

d. Conclusion

89. The evidence described above demonstrates that J&J was actively engaged in a sensemaking process with regard to the quality and safety of its baby powder. J&J's "map" of knowledge started with its commitment to minimizing impurities in its talc to maximize the quality and safety of its product. J&J was in a unique position to monitor and affect its operations, including by an extensive assessment of talc sources, through which J&J also developed its sensemaking capabilities. J&J was simultaneously attentive to the external environment, and in particular, to early concerns regarding the health effects of exposure to asbestos. These behaviors led to J&J's early detection of changes in knowledge that could potentially affect its "map" regarding the quality and safety of its baby powder. J&J's early and active engagement with scientific knowledge regarding talc and asbestos pre-dated, and continued through, the intense public attention to these issues that began in 1971, which is described in **Section IV.C.2** below. As confusion, or "disruptive ambiguity,"¹¹⁴ regarding talc safety became more acute, J&J relied on its already sophisticated "map," and devoted increased attention and significant resources to remaining engaged in a sensemaking process.

Vol. 11, No. 2 (1968)); 1971.08.03 – JNJTALC000091975 (providing a definition from the United States Geological Survey for use by the FDA); 1972.08.11 – DX8371 at 2 (discussing a subsequent meeting with the FDA where it "was agreed by all present that the massive form of tremolite should not be considered as asbestos"); 39 Fed. Reg. 24211, 24317-18 (July 1, 1974) (MSHA); 52 Fed. Reg. 41826, 41846 (October 30, 1984) (EPA); 1989.01.13 – DX8045 (U.S. Consumer Product Safety Commission); 57 Fed. Reg. 24310, 24310 (June 8, 1992) (OSHA clarifying that its regulations will only apply to the asbestiform varieties of the asbestos minerals); 2010 – DX9566 at 277 (International Agency for Research on Cancer); 2011.04 – DX9315 at v, vii, 8 (National Institute for Occupational Safety and Health).

¹¹⁰ See 1971.08.03 – JNJTALC000091975 (Memorandum of the FDA's 1971 Asbestos and Talc Symposium). See also **Figure 1**.

¹¹¹ See **Figure 1**.

¹¹² See, e.g., 1971.08.03 – JNJTALC000091975 (providing a definition from the United States Geological Survey for use by FDA); 1972.08.11 – DX8371 at 2 (discussing a subsequent meeting with the FDA where it "was agreed by all present that the massive form of tremolite should not be considered as asbestos").

¹¹³ See, e.g., 1971.08.03 – JNJTALC000091975 (J&J personnel listed as attendees at this FDA symposium on asbestos and talc); 1972.08.11 – DX8371 (J&J personnel listed as attendees at a subsequent meeting with the FDA).

¹¹⁴ See *supra* **Section IV.B.1** for additional discussion on "disruptive ambiguity."

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2. 1971-1973: Johnson & Johnson Responds to a Period of Disruptive Ambiguity Regarding the Safety of Cosmetic Talc

90. Throughout the early 1970s, confusion regarding definitions of asbestos, and how to identify asbestos in talc, collided with a lack of regulatory testing standards and evolving science on these questions.¹¹⁵ There was significant activity within the talc industry and among regulators, scientists, and the press. There were widely divergent perspectives on the central question of the presence of asbestos in talc, driven by variation in knowledge, capability, and incentives across these stakeholders. Disruptive ambiguity is often at the center of attention and action in organizational sensemaking. As I describe below, throughout this period, J&J was committed to resolving this confusion through a sensemaking process focused on the acquisition of scientific knowledge in order to ensure consumer safety. J&J actively engaged with and responded to internal and external stakeholders as part of this process.

a. Allegations of Asbestos Contamination Lead to Confusion among External Stakeholders

91. Consistent with an organization engaged in the sensemaking process, J&J rapidly responded to reports that alleged potential asbestos contamination in cosmetic talc. Specifically, and as I describe below, J&J interacted with Dr. Langer, Dr. Lewin, independent laboratories and researchers, and regulators to collect additional data regarding these claims. Other stakeholders were also engaged in a sensemaking process, and J&J collaborated and frequently participated in discussions with these other stakeholders. These efforts were intended to advance the science – and to promulgate accurate information – related to whether asbestos was present in cosmetic talc.

(1) Dr. Langer and Mount Sinai

92. In 1971, Mount Sinai School of Medicine tested consumer cosmetic products for the New York Environmental Protection Agency (“NY EPA”). In a June 1971 letter to the federal government and a public statement reported by the *New York Post*,¹¹⁶ Jerome Kretchmer, chief of the NY EPA, announced Mount Sinai’s preliminary results on two tests of unidentified brands of talcum powder that “revealed asbestos content ranging from 5 to

¹¹⁵ See 1986.07.11 – DX7214 at 3 (“[During the early 1970s,] the analytical procedures for determining asbestos in talc were not fully developed, and most of the analytical work was conducted without scientific agreement as to which methods were well-suited for the identification of asbestiform minerals in talc. Consequently, FDA considered all analytical results to be of questionable reliability.”).

¹¹⁶ See 1971.06.29 – JNJALC000298773; 1971.06.30 – DX8369.

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25 per cent.”¹¹⁷ However, he noted those findings were “tentative” and “conceded he could offer no proof that breathing asbestos fibres in baby powder was harmful.”¹¹⁸

93. In response to these allegations, J&J gathered data regarding Mount Sinai’s testing, and learned that one of the allegedly positive tests was from a J&J product. J&J discovered this was a can from Lot #344L and immediately began testing this lot of talc.¹¹⁹ Within one week of the allegations, J&J collected reports on its talc sources from the Colorado School of Mines Research Institute (“CSMRI”) and Dr. R.C. Reynolds of Dartmouth College, and sent them to the FDA.¹²⁰ It also commissioned Dr. Fred Pooley of University College (Cardiff) – a global leader in the study of talc,¹²¹ Walter C. McCrone Associates (“McCrone”) – widely considered the world’s leading microscopy lab,¹²² and CSMRI¹²³ to each test the company’s talc.¹²⁴ Before this testing had concluded, J&J

¹¹⁷ 1971.06.30 – DX8369.

¹¹⁸ 1971.06.30 – DX8369.

¹¹⁹ See 1976.06.04 – DX7125; see also 1971.07.08 – DX10070.

¹²⁰ See 1971.07.08 – DX10070. CSMRI had already been working with Johnson & Johnson to develop analytical techniques to measure talc particles in connection with removing the “fines” of talc from floated talc, which if successful, would improve the feel of the product. See 1971.07.02 – JNJ TALC000291167. See also DX8368 (listing J&J talc correspondence with and submissions to the FDA between 1971 and 1979, including the July 8, 1971 submission of reports by CSMRI and Dr. Reynolds).

¹²¹ See 1971.07.09 – JNJ 000260501 at 503 (“For everyone’s information, we now have Dr. Poole [sic] in England (recognized by Selikoff as an expert) looking at our talc for asbestos.”); 1971.09 – JNJ 000232952 at 861 (“Dr. F. Pooley, the acknowledged world expert in identification of asbestos in minerals and human tissue, has been retained to supervise the sampling of the talc ore and its bedrock.”); 1976.05.13 – JNJ 000252934 at 934 (“JOHNSON’S* Baby Powder has been examined by three (3) independent laboratories: The Colorado School of Mines, McCrone Laboratories in Chicago and by Professor F. Pooley (noted as one of the foremost experts in the field of mineral analysis) of the University of Wales.”).

¹²² See, e.g., 1971.07.09 – JNJ 000260501 at 503 (“We will have Dr. McCrone, whom the FDA recognizes as an expert, looking at our powder starting next Monday.”); 1973.04.20 – DX8265 at 7 (Johns-Manville letter noting that “[o]ne must recognize that Walter C. McCrone Associates, Inc. is one of the finest, if not the best, independent consulting laboratory in the field of microscopy and particle identification”). See also “McCrone Associates,” *Jeol USA Inc.*, available at <https://www.jeolusa.com/APPLICATIONS/REALab-Customer-Stories/McCrone-Associates> (last visited April 11, 2024) (“Founded in 1956 and located in Westmont, Illinois for the past twenty years, The McCrone Group, Inc., has become internationally recognized as a world leader in microscopy, microanalysis, materials characterization, and consulting.”).

¹²³ See JNJNL61_000009023 at 024 (“The Research Foundation is uniquely suited for its part in the continuing development of the world’s mineral industries... A completely separate, independent, and not-for-profit corporation, the Foundation is joined traditionally and, to some extent, physically to the Colorado School of Mines - long recognized everywhere as a leading center of mineral industrial technology.”).

¹²⁴ See 1971.08.10 – DX7017 at 9 (Pooley) (Although Dr. Pooley found “one small Chrysotile fibril,” he concluded that “the Chrysotile content of the samples examined can be considered as nil” because “background contamination of one fibril per E.M. field is normal” in “most laboratories.”); 1971.08.19 – DX7019 (McCrone); 1971.08.06 – DX7014 (Colorado School of Mines).

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directed that “full information” be provided to the FDA.¹²⁵ Each of these reports found no asbestos detected from the samples.¹²⁶

94. J&J scientists met with Mount Sinai’s Dr. Langer to discuss his findings. According to J&J’s record of that meeting, Dr. Langer stated that the presence of fibrous materials in his results “could be ‘asbestos’” – a different characterization than what the press reported.¹²⁷ In J&J scientists’ opinion, “[N]either true quantitative nor qualitative analysis was performed.”¹²⁸
95. As a result of its early discussions with Mount Sinai, J&J quickly acknowledged the need for a “good report outlining talc and asbestos” because the discourse surrounding the mineralogy of talc was “too much of a confused mess” at the time.¹²⁹ As a scientific article on talc would later remark, “[s]ome of the controversy and confusion about talc can be attributed to the loose application of the term ‘talc’ for widely varying mixtures of components of different pathogenicity.”¹³⁰
96. As regulators, scientists, and the industry worked to address this confusion over the next few years,¹³¹ the press published another article based on Dr. Langer’s preliminary testing – now in *The New York Times*.¹³² J&J immediately followed up with the FDA and Dr. Langer regarding the article and those same preliminary test results.¹³³ Dr. Langer expressed that he and Mount Sinai “were furious about the article since they have not been consulted before publication.”¹³⁴ The next day, Dr. Langer then provided a public statement in an article entitled “Doctor Admits He May Have Been Mistaken,” saying he “foolishly” sent his original report after only looking at two samples: “The data were very

¹²⁵ 1971.07.09 – JNJ 000086522; *see also* 1972.12.13 – DX7054 at 1 (“I explained that from the beginning our company’s attitude and actions had been to share information with the FDA in order to prevent unnecessary panic and irrational actions due to any ill-formed consumer pressures. We had, I pointed out, provided information and offered our complete background files to the administration prior to the public disclosures in this country of any concerns about talc per se or the potential contamination of talc with asbestos.”). *See also* DX8368 (listing J&J talc correspondence with and submissions to the FDA between 1971 and 1979, including the September 21, 1971 submission of reports by CSMRI, Dr. Pooley, and McCrone).

¹²⁶ *See* 1971.07.21 – DX8203.

¹²⁷ 1971.07.09 – JNJ 000260510 at 513.

¹²⁸ 1971.07.09 – JNJ 000260510 at 515. *See also* June 4, 2020 Interview of Dr. John Hopkins.

¹²⁹ 1971.07.09 – JNJ 000284105.

¹³⁰ Wehner, A. P., et al. “Inhalation of talc baby powder by hamsters,” *Food and Cosmetics Toxicology*, Vol 15, No. 2 (1977), pp. 121, 128.

¹³¹ *See, e.g.*, 1971.08.03 – DX7013 (August 3, 1971 FDA’s Asbestos and Talc Symposium).

¹³² Lichtenstein, Grace, “High Levels of Asbestos Found in 3 Paints and 2 Talcums Here,” *The New York Times*, June 16, 1972, available at <https://timesmachine.nytimes.com/timesmachine/1972/06/16/79471048.pdf>.

¹³³ *See* 1972.06.17 – JNJ 000086525. *See also* 1972.06.20 – JNJ 000314709.

¹³⁴ 1972.06.17 – JNJ 000086525 at 525.

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preliminary in nature, and... I may have mistaken long talcum fibers for asbestos fibers.”¹³⁵ *The New York Times* corrected its story in an article titled “Talc Warning Is Labeled False.”¹³⁶

(2) Dr. Lewin and the FDA

97. In the midst of the disruptive ambiguity that was precipitated by the publication of Mount Sinai’s preliminary findings, the FDA hosted a symposium in August 1971 on “Asbestos and Talc,” which was central to the discussion and dissemination of scientific knowledge regarding cosmetic talc safety. More than 40 scientists, physicians, regulators, and consumers from both industry and government, including J&J personnel, attended the 1971 Symposium.¹³⁷ Attendees “generally agreed that most talcum powders of major manufacturers are relatively free of asbestos.”¹³⁸ However, the Symposium also raised important questions about (1) the medical significance of asbestos and other fibers at low levels and (2) the analytical methods for analyzing cosmetic talc for the presence of asbestos.¹³⁹
98. Following the confusion caused by Mount Sinai’s preliminary findings and the questions coming out of the FDA’s 1971 Symposium, the FDA took additional steps to resolve the disruptive ambiguity involving potential asbestos contamination in cosmetic talc. In response to Mount Sinai’s preliminary findings and Mr. Kretchmer’s request to investigate the issue of asbestos in talc, in December 1971, the FDA commissioned Dr. Seymour Lewin, a chemistry professor at New York University, to analyze commercial talc products.¹⁴⁰ In mid-1972, Dr. Lewin asserted that he also found asbestos in Johnson’s Baby Powder and Shower to Shower Body Powder, among many other manufacturers’

¹³⁵ 1972.06.17 – DX7032. Dr. Langer would maintain in conversations with J&J and others that Mount Sinai did in fact identify “traces” of asbestos in J&J’s talc. *See* 1971.06.19 – JNJ 000260529; 1976.03.15 – JNJ 000030487. No such evidence appears in the peer-reviewed paper he co-authored with others at Mount Sinai. *See* 1976 – DX8096; 1975.11.21 – DX8240 (identifying which samples were tested).

¹³⁶ Lichtenstein, Grace, “Talc Warning Is Labeled False,” *The New York Times*, June 17, 1972, available at <https://timesmachine.nytimes.com/timesmachine/1972/06/17/83447467.pdf>.

¹³⁷ *See* 1971.08.03 – DX7013 (J&J Memorandum of Symposium); 1971.08.11 – DX9107 (FDA Memorandum of Symposium).

¹³⁸ 1971.08.03 – DX7013 at 1.

¹³⁹ *See* 1971.08.03 – DX7013. *See also* **Figure 4**.

¹⁴⁰ *See* 1973.07.31 – DX7068.

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products, using an x-ray diffraction (“XRD”) method¹⁴¹—a method which is incapable of distinguishing the asbestiform varieties of the asbestos minerals.¹⁴²

99. As they did when faced with Mount Sinai’s preliminary report, J&J scientists and other independent scientists investigated and ultimately concluded that Dr. Lewin’s results were incorrect.¹⁴³ J&J met with Dr. Lewin and the FDA regarding the alleged high level of chrysotile asbestos in J&J’s Shower to Shower product.¹⁴⁴ Dr. Lewin agreed to reexamine samples using a different, petrographic optical technique, and again claimed to find chrysotile in J&J samples.¹⁴⁵ Then, Walter McCrone, a renowned microscopist, visited Dr. Lewin to understand the methods he used and concluded that “[h]e is on shaky ground when he identifies [certain images] as chrysotile.”¹⁴⁶ McCrone later showed those particles to be “calcium silicate,” not chrysotile.¹⁴⁷ Similarly, according to an XRD laboratory fellow at Carnegie Mellon University, “Dr. Lewin indicated his lack of fundamental understanding of crystallography” during a meeting with the FDA.¹⁴⁸ An FDA microscopist concurred, noting that “Dr. Lewin was wrong and... was ‘outside his field of competence.’”¹⁴⁹
100. Consistent with what I would expect of an organization engaged in sensemaking, J&J sought additional perspectives from outside of J&J in order to make sense of the allegations. McCrone, professors at Massachusetts Institute of Technology and Princeton University, CSMRI, and Dr. Pooley, among others, tested Shower to Shower.¹⁵⁰ All of these investigations, which included XRD, differential thermal analysis (“DTA”), and the

¹⁴¹ See 1972.08.03 – DX10118; 1972.09.26 – JNJ 000232996. See also 1972.09.25 – DX8708; 1972.10.17 – DX8372; 1972.11.29 – DX7053. I note that Dr. Lewin detected no asbestos in other Johnson’s Baby Powder and Medicated Powder samples tested. See 1972.08.03 – DX10118 (finding no asbestos minerals in products #29 and #30).

¹⁴² See 1984 – JNJ 000224493 at 502 (“The instrument [X-ray diffraction], however, cannot differentiate between fibrous and nonfibrous minerals.”).

¹⁴³ See 1972.08.11 – DX8371.

¹⁴⁴ See 1972.09.25 – DX8708.

¹⁴⁵ See 1972.10.17 – DX8372 at 165-166 (Professor Buerger (MIT): “There can be no doubt that ‘Shower-to-Shower’ talcum as made by Johnson & Johnson is not contaminated by any appreciable amount of chrysotile asbestos. With this background, it was a shock to hear Professor Lewin say that, while he agreed with these results, he now relied on certain optical tests which proved that chrysotile was really present in substantial quantities in ‘Shower-to-Shower.’”); see also 1972.10.17 – DX8372 at 203 (Professor Brown (Princeton): “That Professor Lewin is a polished speaker is not questioned... however, his interpretation and command of the theory of x-ray diffraction and optics is suspect... Neither Lewin’s x-ray data nor his optical data supports his claim that chrysotile is present in Shower-to-Shower.”).

¹⁴⁶ 1972.10.09 – DX8705 at 1.

¹⁴⁷ 1972.10.09 – DX8705 at 2.

¹⁴⁸ 1972.10.09 – DX8705 at 7.

¹⁴⁹ 1972.12.13 – DX7054 at 1.

¹⁵⁰ See 1972.10.17 – DX8372; 1972.09.25 – DX8708.

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more sensitive transmission electron microscopy (“TEM”),¹⁵¹ “failed to establish any chrysotile asbestos.”¹⁵² Similarly, McCrone, CSMRI, Princeton University, Dr. Pooley, and J&J’s internal laboratory all analyzed samples of Johnson’s Baby Powder from the allegedly contaminated lots (108T and 109T) and did not affirmatively identify asbestos.¹⁵³

101. J&J scientists met with the FDA to discuss these test results and later submitted its reports to the FDA.¹⁵⁴ J&J also wanted to share this testing data with the CTFA so that the CTFA could also confirm with the FDA that the data was the “most accurate and sophisticated available.”¹⁵⁵ Among other issues, it appeared that Dr. Lewin had mistaken common chlorite for the asbestos mineral chrysotile.¹⁵⁶

(3) Other Allegations of Asbestos Contamination

102. During this period of disruptive ambiguity, other individuals and organizations also became involved in testing cosmetic talc for the presence of asbestos. For some, their interest with cosmetic talc began in connection with the FDA’s investigation into Dr. Langer’s and Dr. Lewin’s results. Others took an academic interest in consumer talc products. As I describe below, many of these individuals or organizations seemingly lacked relevant expertise and as a result, added to the disruptive ambiguity regarding whether cosmetic talc products were contaminated with asbestos. J&J engaged with the science and ongoing testing in order to ensure that its understanding accurately reflected the available scientific knowledge.

103. In 1972, as part of the testing conducted in response to Dr. Lewin’s results, McCrone also commissioned Dr. Thomas Hutchinson at the University of Minnesota to analyze a

¹⁵¹ See 1990 – DX9666 at 5-6 (“To meet [0.1% asbestos] standard, a more sensitive method to detect asbestos is needed. Such low levels are not quantifiable by polarized light microscopy and the morphology is not discernable by x-ray diffractometry. Transmission electron microscopy is capable of detecting these low levels.”); 1973.12.11 – DX7079.

¹⁵² 1972.10.17 – DX8372 at 2; 1972.09.25 – DX8708; 1973.11.09 – DX7078; 1973.03.14 – DX8241.

¹⁵³ See 1972.11.29 – DX7053. J&J did disclose the presence of a “few tremolite rods” found by McCrone, although McCrone did not affirmatively identify them as asbestiform tremolite. See 1972.11.29 – DX7053 at 21. Earlier testing by McCrone attempted to quantify those results, but McCrone could not substantiate them. See 1972.11.15 – DX7052 (“After looking at several fresh samples on the light microscope we have not been able to substantiate the tremolite levels we originally reported.”); 1972.10.27 – DX8391 (earlier version of McCrone’s report).

¹⁵⁴ See 1972.09.25 – DX8708; 1972.09.26 – DX7041; 1972.10.17 – DX8372; 1972.11.29 – DX7053. See also DX8368 (listing J&J talc correspondence with and submissions to the FDA between 1971 and 1979, including the September 21, 1972 meeting as well as the October 17, 1972 and the November 29, 1972 submissions regarding Shower to Shower and Johnson’s Baby Powder, respectively).

¹⁵⁵ See 1972.10.30 – JNJTALC000290357.

¹⁵⁶ See 1972.09.26 – DX7041; 1972.10.17 – DX8372 at 222-223; 1975.09.12 – JNJTALC000439376.

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“Lewin” sample using scanning electron microscopy (“SEM”).¹⁵⁷ Dr. Hutchinson’s results supported McCrone’s opinion that “SEM is not a valid technique for the identification of asbestos in talc.”¹⁵⁸ He also purported to analyze the “Lewin” sample as well as a sample of Shower to Shower by TEM for the presence of asbestos but there were numerous questions and concerns regarding his methodology and his testing results.¹⁵⁹ Later, Dr. Hutchinson conceded that the project was hectic.¹⁶⁰ J&J shared McCrone’s report with the FDA, which included Dr. Hutchinson’s conclusions regarding SEM but not TEM. McCrone, the premier TEM lab at the time, had performed its own TEM testing (among other examination techniques) and concluded, “None of the techniques employed... revealed any trace of chrysotile... [T]he original report of chrysotile... is erroneous.”¹⁶¹

104. Sperry Rand was another organization that analyzed one of Dr. Lewin’s samples by SEM. Like Dr. Hutchinson, its personnel initially claimed to identify “asbestos fibers” in the sample.¹⁶² J&J noted that these results were “completely at variance with the information [it had] from McCrone and from [its] laboratories,” and immediately followed up with the FDA and Mr. Wehrung of Sperry Rand.¹⁶³ After speaking with Mr. Wehrung, J&J learned that “no identification could be made” of the fibers and “that he could only state they had the ‘asbestos form’.”¹⁶⁴ In a letter to J&J one week later, Mr. Wehrung explained the misunderstanding: he incorrectly referred to the particles as “‘asbestosform’ and which may more correctly be called ‘fiber-form’” because “the scanning electron microscope and energy dispersive X-ray analyzer are not able to positively identify chrysotile or any form of asbestos.”¹⁶⁵

105. During this time, J&J continued to monitor external research and interacted with scientists who wrote about talc. For example, in 1972, two graduate students and their faculty advisor at Bowling Green State University authored an article titled

¹⁵⁷ 1972 – JOJO-MA2546-01282.

¹⁵⁸ 1973.06.22 – DX8154.

¹⁵⁹ See 1972 – JOJO-MA2546-01282; 1972.08.30 – DX8068; 1972.10.05 – DX8407; 1972.09.28 – DX8015.

¹⁶⁰ See 1972.11.29 – JOJO-MA2546-01365. For example, Dr. Hutchinson claimed to have spent at most four hours on TEM to while also analyzing approximately 3,000 grid squares whereas J&J’s TEM method required two hours to analyze approximately 10 grid squares. See 1972.09.28 – DX8015; Undated – DX8016. See also 1989.03.08 – JNJ 000291563 (J&J TEM specification calling for two hours of analysis per ten grid squares).

¹⁶¹ 1973.06.22 – DX8154 at 2; 1973.11.09 – DX7078.

¹⁶² 1972.08.24 – JNJ 000270070.

¹⁶³ 1972.08.24 – JNJ 000270070 at 070; see also 1972.08.31 – DX8025; June 4, 2020 Interview of Dr. John Hopkins.

¹⁶⁴ 1972.08.31 – DX8025.

¹⁶⁵ 1972.09.08 – DX8817.

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“Asbestosform Impurities in Commercial Talcum Powders,” which was published in a journal that disseminated student-led research.¹⁶⁶ They concluded, “18 commercial talcum powders examined contained from 4% to 46% asbestiform minerals.”¹⁶⁷ Johnson’s Baby Powder was found to contain 8% asbestiform minerals.¹⁶⁸ At J&J’s request, CSMRI personnel reviewed the Bowling Green paper, identified a number of potential errors, and spoke with the authors to discuss their results. During this discussion, the authors acknowledged they had no previous experience with talc mineralogy, “readily admitted that they did a ‘rush-job’,” and made errors in identification by both XRD and optical microscopy, which likely led to misidentifying chlorite and talc as asbestos.¹⁶⁹ The paper remained publicly available, and was subsequently cited in a Citizen’s Petition to the FDA, to which the FDA responded that it agreed with CSMRI’s conclusions regarding the Bowling Green paper.¹⁷⁰

106. In 1973, the Dutch Consumer Organization also analyzed J&J’s talc by SEM and reached out to an international J&J affiliate claiming to find asbestos in Johnson’s Baby Powder on two occasions.¹⁷¹ J&J worked to obtain permission to speak with the laboratory that performed the testing and discuss the results.¹⁷² Prior to that meeting, it was clear there were many issues with the testing: the lab had used an inaccurate definition of asbestos and an inappropriate method for identifying asbestos. By the lab’s definition of asbestos, the common mineral impurity chlorite would be called asbestos, as indeed would talc itself, but any asbestiform varieties of tremolite and anthophyllite would not.¹⁷³ As discussed above, SEM would not be able to positively identify asbestiform minerals.¹⁷⁴

¹⁶⁶ See 1972.01 – JNJTALC000286977; 1973.06.08 – DX8726. See also “About Us,” *The Society of Sigma Gamma Epsilon*, available at <https://sgearth.org/about/> (“Members of Sigma Gamma Epsilon are encouraged to submit articles to the Society’s professional journal, *The Compass*, as it provides the opportunity to share your research with the Society. *The Compass* contains student papers and articles by practicing earth scientists in addition to news and notes about the Society.”).

¹⁶⁷ 1973.06.08 – DX8726 at 1.

¹⁶⁸ See 1972.01 – JNJTALC000286977; 1973.06.08 – DX8726 at 5.

¹⁶⁹ 1973.06.08 – DX8726.

¹⁷⁰ See 1986.07.11 – DX7214 at 4 (“FDA should also point out that, in reviewing your petition, we found several problems with the information on which you relied. The publication ‘Asbestosform Impurities in Commercial Talcum Powders,’ which you cite in your petition, appears to contain a number of significant errors that lead us to question the accuracy of the findings that you reported. For your information, we have enclosed a copy of a June 8, 1973, rebuttal of this publication that was written by the Chief Mineralogist of the Colorado School of Mines Research Institute in Golden, Colorado.”), 22-27.

¹⁷¹ See 1973.12.13 – JNJTALC000376583; see also 1973.09.20 – DX7070.

¹⁷² See 1973.12.13 – JNJTALC000376583.

¹⁷³ 1973.09.20 – DX7070 at 2-3. See also **Figure 1** for information on tremolite and anthophyllite.

¹⁷⁴ See 1973.09.20 – DX7070 at 3; see also 1972.09.08 – DX8817 (noting that “the scanning electron microscope and energy dispersive X-ray analyzer are not able to positively identify chrysotile or any form of asbestos”).

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107. J&J devoted significant attention and resources to clarify, interpret, and discuss new scientific knowledge regarding the identification of asbestos in cosmetic talc. The actions described above demonstrate J&J's commitment to articulating and disseminating factually accurate scientific knowledge regarding the safety of its baby powder. J&J's efforts to avoid public confusion are consistent with this commitment and with active engagement in a sensemaking process.

b. Understanding the Sources of the Disruptive Ambiguity

108. Sensemaking is an ongoing activity that is most visible or explicit in moments of uncertainty.¹⁷⁵ For J&J, its sensemaking capabilities were focused on understanding the reasons behind Dr. Langer's and Dr. Lewin's results, as well as why their results contradicted the results of other experts. J&J and others broadened their inquiries and identified topics relevant to talc safety more generally. By August 1972, J&J had already conducted, sponsored, or was otherwise affiliated with at least 52 completed reports related to physical, animal, and clinical talc studies dating back to 1957.¹⁷⁶ Yet, J&J and others recognized the need to further disambiguate the "controversy and confusion" around talc.

(1) Multiple and Conflicting Regulatory Definitions

109. During the confusion of the 1970s over asbestos in talc, J&J and others faced regulatory uncertainty that threatened, often unintentionally, to prevent talc from ever being used as an ingredient. J&J responded by publicly engaging with the relevant authority and demonstrating the unintended consequences of the proposed regulations.

110. In 1972, the FDA's Bureau of Foods considered banning any "asbestos-form particles" in talc, a term that the agency later proposed be defined by the particle's aspect ratio,¹⁷⁷ effectively banning talc that can appear to have the shape of a fiber under the microscope.¹⁷⁸ That proposal relied on a 1971 article by Dr. Reuben Merliss which

¹⁷⁵ See *supra* Section IV.B.1.

¹⁷⁶ See 1972.08.02 – JNJ 000273388; see also 1957.10.15 – DX8381; 1958.01.24 – DX8337; 1958.05.09 – DX8382; 1958.05.23 – DX8383; 1959.07.31 – DX8384; 1959.08.31 – DX8385; 1959.09.15 – DX8386; 1959.12.31 – DX8387; 1960.01.31 – JNJ 000235502; 1960.03.08 – DX8388; 1960.04.12 – DX8389; 1961.06.06 – JNJ TALC000129140; 1961.09.18 – JNJ 000087710; 1963.05.27 – JNJ 000087425; 1966.04.07 – JNJ 000087299; 1968.01.24 – JNJ 000087825.

¹⁷⁷ See 37 Fed. Reg. 16408 (Aug. 12, 1972); 38 Fed. Reg. 27080 (Sept. 28, 1973).

¹⁷⁸ See 1972.10.11 – JNJ 000244639 at 641 ("'Asbestos-form particles,' a vague description not generally used in scientific communications, can be interpreted to include elongated talc fragments, rolled platelets of talc, and textile and paper fibers. We know of no process that guarantees total removal of all elongated particles from talc."); 1973.03.14 – JNJ 000233357 (discussing the FDA's plan and noting "OSHA Regulations define asbestos fibers as being any fiber within a length/breadth ratio of 3 to 1. If this description for

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hypothesized that asbestos-contaminated talc may be carcinogenic based on an increased rate of stomach cancer among the Japanese.¹⁷⁹ The hypothesis was questioned by others familiar with the Japanese diet who identified other causes they believed more likely and noted the “negligible” amounts of talc involved.¹⁸⁰ Nevertheless, J&J invested in improving its flotation processes “to better select platy talc, and perhaps reduce any tremolite or talc shards.”¹⁸¹

111. There was also confusion around terminology with respect to asbestiform and non-asbestiform minerals; certain minerals, such as tremolite and actinolite, come in both asbestiform and non-asbestiform varieties but use the same name.¹⁸² For example, the industry faced uncertainty around this issue from OSHA regarding what minerals were regulated as asbestos. OSHA’s original regulations stated, “‘Asbestos’ includes chrysotile, amosite, crocidolite, tremolite, anthophyllite, and actinolite,” without distinguishing between the massive and asbestiform varieties.¹⁸³ In 1972, when the R.T. Vanderbilt Company petitioned OSHA to exclude from its standard the non-asbestiform varieties of anthophyllite and tremolite, OSHA ultimately refused to modify its procedures accordingly (although it did not amend its regulations to specifically cover the non-asbestiform minerals either).¹⁸⁴ Internally, OSHA appeared to believe, according to a 1974 statement by Assistant Secretary John Stender, that “[n]onfibrous or non-asbestiform minerals such as non-asbestiform tremolite are not within the scope of the existing standard.”¹⁸⁵ OSHA then revised its position, based on preliminary data from an occupational study conducted by NIOSH, and as described in a 1977 letter from OSHA to the R.T. Vanderbilt Company.¹⁸⁶ It was not until 1992 that OSHA made public an official stance, in which OSHA modified its definition of asbestos to exclude the non-asbestiform varieties of the asbestos minerals: “Based on the entire rulemaking record before it, OSHA has made a determination that substantial evidence is lacking to

asbestos is adapted to talc, it will be of great concern to us and others as many talc particles will be in a ratio of 3 to 1.”); 1973.04.26 – JNJ 000294872 (discussing the Bureau of Foods’ position and how it would relate to current quality control and talc improvement processes).

¹⁷⁹ See 1972.10.11 – JNJ 000244639 (discussing Merliss, R.R., *Talc-treated Rice and Japanese Stomach Cancer*, 173 Science 1141 (Sept. 17, 1971)).

¹⁸⁰ 1972.10.11 – JNJ 000244639 at 642 (“Merliss had based his hypothesis on the incidence of stomach cancer among Japanese, some of whom are believed to eat rice coated with talc contaminated by asbestos; others equally knowledgeable about the diet of Japanese disagree and believe other causes of the malignancies are more likely.”).

¹⁸¹ 1973.04.26 – JNJ 000294872.

¹⁸² See **Figure 1**.

¹⁸³ 37 Fed. Reg. 11318, 11320 (June 7, 1972).

¹⁸⁴ See 57 Fed. Reg. 24310, 24314 (June 8, 1992). See **Figure 1** for additional information on the massive and asbestiform varieties.

¹⁸⁵ 1974.08.06 – JNJ 000325851. See also 1986 – JNJTALC000216929.

¹⁸⁶ See 1977.01.19 – JNJ 000044334.

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conclude that nonasbestiform tremolite, anthophyllite and actinolite present the same type or magnitude of health effect as asbestos.”¹⁸⁷

**(2) The FDA Identifies Confusion over Testing
Methodologies and Terminology as the Source of
Disruptive Ambiguity**

112. Although the FDA originally commissioned Dr. Lewin to assess current talc products in response to allegations by Mount Sinai and the NY EPA, his testing led to more questions than answers. In August 1972, following the preliminary report by Dr. Lewin, the FDA met with J&J and other scientists to discuss the findings.¹⁸⁸ Dr. Lewin expressed his confusion at the incongruous results between McCrone’s lab and his own, and could not reach agreement with others regarding the interpretation of x-ray data.¹⁸⁹ It became clear that there was a lack of consensus on how to test and what certain test results meant.

113. In September 1972, at a second meeting with the FDA and Dr. Lewin, independent consultants for J&J presented data that they believed “[were] now conclusive and contain[ed] new information on the composition of Italian talc which may explain the errors of Dr. Lewin.”¹⁹⁰ Following unanimous criticism by multiple experts of Dr. Lewin’s results, it appeared that Dr. Robert Schaffner (an FDA Director) was “now fairly convinced that Dr. Lewin’s findings are not reliable,” and a new testing procedure using optical microscopy was requested by all.¹⁹¹

114. Dr. Lewin then reexamined his samples according to an agreed-upon procedure.¹⁹² He failed to positively identify any tremolite or chrysotile in any J&J sample, and only noted a “?” regarding chrysotile in sample #84 (the Shower to Shower sample) and “trace” tremolite in #131 (Medicated Powder); additionally, the tremolite was found by XRD which does not distinguish tremolite asbestos from other forms of tremolite.¹⁹³

115. Following a February 26, 1973 *Wall Street Journal* article regarding the presence of asbestos-type impurities in cosmetic powders, Dr. Lewin subsequently clarified his

¹⁸⁷ 57 Fed. Reg. 24310 (June 8, 1992). *See also* **Figure 4** for a timeline of industry definitions of asbestiform particles and testing procedures, including OSHA.

¹⁸⁸ *See* 1972.08.14 – JNJ TALC000289154. *See also* June 4, 2020 Interview of Dr. John Hopkins.

¹⁸⁹ *See* 1972.08.14 – JNJ TALC000289154.

¹⁹⁰ 1972.09.25 – DX8708 at 1. *See also* June 4, 2020 Interview of Dr. John Hopkins.

¹⁹¹ 1972.09.25 – DX8708 at 3.

¹⁹² *See* 1972.10.09 – DX8705; Undated – DX7066.

¹⁹³ *See, e.g.*, 1984 – JNJ 000224493 at 167 (“The instrument [X-ray diffraction], however, cannot differentiate between fibrous and nonfibrous minerals.”). *See also* **Figure 1** for further information on asbestiform and non-asbestiform tremolite and **Figure 3** for further information on XRD; Undated – DX7066 at 5, 7, 9, 14-15.

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statements regarding the presence of asbestos in J&J powders.¹⁹⁴ In a letter to the editor of the *Wall Street Journal*, he stated: “In the article referred to, I was erroneously quoted as having reported that Johnson & Johnson’s talcum powder contained 2% to 3% asbestos. In actual fact, I reported that of 11 samples of the [J&J talc], I found no evidence of asbestos in nine of the samples, and the other two samples fell into the inconclusive category.”¹⁹⁵

c. Johnson & Johnson Explores Cornstarch-Based Baby Powder

116. J&J had first considered marketing a cornstarch-based baby powder in 1964, prior to the disruptive ambiguity regarding the safety of talc-based baby powder in the early 1970s.¹⁹⁶ In the early 1970s, methodological confusion over testing and terminology regarding talc safety, and the potential for regulatory definitions that would potentially affect all talc products, J&J began a second phase of active development of a cornstarch-based baby powder.¹⁹⁷ At the time, J&J noted the “attacks on talc are confused by questions on the presence or absence of asbestos or other particles of needle-like form,” and viewed a possible cornstarch-based product as either “a replacement in [event] of a crisis or as an extension product.”¹⁹⁸

117. From a sensemaking perspective, this is the type of activity I would expect to see occur in the face of disruptive ambiguity. That is, J&J acknowledged and openly discussed the impact that the disruption would potentially have on its organization and its customers. It thought about alternative outcomes as a result of the disruption, and it planned for more than one of these alternative outcomes as an eventuality.¹⁹⁹ In fact, I would be concerned

¹⁹⁴ See 1973.03.12 – DX7058; 1975.01 – DX8264 at 11.

¹⁹⁵ 1973.03.12 – DX7058.

¹⁹⁶ See 1973.01.31 – DX8292.

¹⁹⁷ See 1973.01.31 – DX8292 at 2 (“During the second phase of development which began in July 1971 and is active presently...”); 1972.12.05 – JNJ 000264042 (“We have decided to proceed to test market of current corn starch product.”).

¹⁹⁸ 1972.12.05 – JNJ 000264042; 1973.01.31 – DX8292 at 2 (“During the second phase of development which began in July 1971 and is active presently, the effort was directed at duplicating Johnson’s Baby Powder (talc) with a biodegradable powder either as a replacement in even [sic] of a crisis or as an extension product.”).

¹⁹⁹ See 1971.11.16 – JNJ 000221528 (“A program has been started with the highest priority in the Biopharmaceutics group to evaluate materials for substitution of talc in baby powder.” J&J investigated talc substitutes including additives to corn starch, rice starch, and other natural and modified starches).

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if instead, J&J had maintained a singular focus on the status quo in the face of the disruptive ambiguity of this period.²⁰⁰

118. J&J approved Johnson's Baby Powder with Cornstarch for national sale in 1978. It was not introduced as a replacement for talc-based powders, because by that time much of the ambiguity and concern regarding the safety of cosmetic talc had been resolved.²⁰¹ Instead, it was an option for consumers who preferred cornstarch's different properties.²⁰² Consumers have had a choice among the talc-based or the cornstarch-based baby powder for more than 40 years. The fact that J&J's cornstarch product was discussed as a result of the disruptive ambiguity of the early 1970s is not extraordinary. It is the type of activity that is well documented in the literature on organizations with robust sensemaking processes.

d. Conclusion

119. In my opinion, J&J's initial response to the substantial confusion surrounding asbestos and talc illustrates a pattern of "best practices" in the process of sensemaking.²⁰³ J&J did not ignore or disengage from the disruptive ambiguity, but rather took steps to seek external knowledge and engage with regulators and the scientific community. J&J also sought to understand the motivations and intentions of outside stakeholders, such as

²⁰⁰ Exploring substitute actions is consistent with the process of sensemaking. *See, e.g.,* Weick, Sutcliffe, and Obstfeld (2005), p. 409 ("Explicit efforts at sensemaking tend to occur when the current state of the world is perceived to be different from the expected state of the world, or when there is no obvious way to engage the world. In such circumstances there is a shift from the experience of immersion in projects to a sense that the flow of action has become unintelligible in some way. To make sense of the disruption, people look first for reasons that will enable them to resume the interrupted activity and stay in action. These "reasons" are pulled from frameworks such as institutional constraints, organizational premises, plans, expectations, acceptable justifications, and traditions inherited from predecessors. If resumption of the project is problematic, sensemaking is biased either toward identifying substitute action or toward further deliberation.").

²⁰¹ *See* 1978.10.03 – JNJ 000349806 at 806 ("To date, there have been no reports on any clinical concerns from the test market areas, and therefore, formula #3552-41-01 is approved for national sale."); *see also* 1978.08.23 – DX8231 at 3 ("Johnson's Corn Starch should assume a market position distinct from other products on the market, especially Johnson's Baby Powder.").

²⁰² *See* 1973.01.31 – DX8292 at 3 ("The properties of corn starch and other powders did not duplicate those of talc but had unique and desired properties of their own. Corn Starch Baby Powder is more absorbent, whiter, more flowable, apparently able to retain perfume better than the talc product."); 1973.01.31 – DX8292 at 4 (noting a product test where Johnson's Corn Starch was preferred to Johnson's Baby Powder and other cornstarch products in a blind study).

²⁰³ *See supra* Section IV.B.1.

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regulators and the scientific community, in order to better understand their perspectives.²⁰⁴

120. As new knowledge became available, J&J updated its “map” and communicated it with regulators and the scientific community in the interest of sharing it widely and inviting others to challenge its understanding. As this process unfolded, some of the key figures who instigated the disruptive ambiguity abandoned their stances and acknowledged the safety of cosmetic talc, reaffirming J&J’s “map.”²⁰⁵ In fact, McCrone and the FDA would later remark that much of the testing from this time period was incorrect or suspect, or used inappropriate definitions of asbestos.²⁰⁶

121. Furthermore, J&J engaged in its own adaptive sensemaking by continuing to identify gaps in knowledge and to support studies to fill those gaps. It also discussed and explored alternative strategies in the face of the existing uncertainty. These efforts demonstrate that, internally, J&J was also having active discussion regarding the disruptive ambiguity it faced, and that it was not responding by simply maintaining the status quo. This is also a “best practice” in organizational sensemaking.

122. As I discuss below, J&J’s diligent effort to monitor and engage with the science surrounding asbestos and talc after this period of disruptive ambiguity allowed it to continue testing its “map,” further develop its sensemaking capabilities, and rapidly respond to new information from the external environment. J&J did this in ways that required a commitment of organizational resources to sensemaking and that were consistent with its organizational priorities oriented to the safety of its products and wellbeing of consumers.

3. Johnson & Johnson Engages in Sensemaking with Industry and Regulatory Stakeholders

123. J&J’s engagement with industry and regulatory stakeholders catalyzed efforts to establish new testing methods. These new testing methods would be capable of identifying

²⁰⁴ “Stakeholder analysis” is a common activity that informs sensemaking in organizations, and is well-documented in the literature on sensemaking. *See, e.g.*, Maitlis and Christianson, pp. 93-94. *See also* Maitlis, Sally, “The Social Processes of Organizational Sensemaking,” *The Academy of Management Journal*, Vol. 48, No. 1, 2005, p. 24.

²⁰⁵ *See Section IV.C.3, infra. See, e.g.*, 1972.04.11 – JNJ 000328233 at 233 (Dr. Selikoff commenting that “no hazard was demonstrated” for “consumer use of talc”); 1972.06.17 – DX7032 (Dr. Langer commenting, “I may have mistaken long talcum fibers for asbestos fibers... It annoys the hell out of me—there are a lot more important things than looking for asbestos in talcum powder,” and noting there was no evidence trace levels could be harmful).

²⁰⁶ *See* 1980 – DX9267 at 8-9 (describing Dr. Lewin’s original report as “grossly wrong” and criticizing Mount Sinai for relying on particle dimension only to identify asbestos); 1986.07.11 – DX7214 at 3 (FDA remarking that it considers “all analytical results [from this period] to be of questionable reliability”).

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asbestos in talc and enable efforts to develop a common understanding of the potential health effects of cosmetic talc exposure. J&J not only devoted significant resources to these efforts for its own baby powder, but also communicated its “map” with external stakeholders and welcomed critical examinations and discussions of its understanding. Contemporaneous documents acknowledge the difficulties inherent in these efforts, and repeatedly demonstrate J&J’s commitment to basing these understandings on newly available scientific knowledge.

124. This period of intense activity led to J&J codifying its “map,” with internal communications documenting the knowledge that entered the organization, J&J’s actions and reactions, and the new understandings that resulted. Below I describe these processes, specifically concerning J&J’s testing, its continued engagement with scientists and regulators to challenge and refine its “map,” and its actions to formalize its robust sensemaking practices for continued use.

a. Johnson & Johnson Collaborates with Industry and Regulatory Stakeholders to Develop New Testing Methods and Quality Control Measures

125. J&J and the talc industry worked with the FDA to develop an industry standard for the definition and identification of asbestos in cosmetic talc. By the mid-1970s, for the first time, the industry, scientists, and regulators began to come to a common understanding around the identification of asbestos and testing procedures capable of identifying its presence in cosmetic talc.²⁰⁷ J&J’s efforts were central to establishing this common understanding and the resultant industry testing standards.

(1) The FDA and the Industry Explore Testing Methods and the Industry Adopts J4-1

126. The 1971 Symposium involving the FDA and the industry brought into focus the lack of an industry-standard test method for analyzing cosmetic talcum products. There, the group of scientists and regulators held “extensive discussions” regarding the methods available to test cosmetic talc, and the FDA announced it was “working on the details of a laboratory procedure for the analysis of asbestos in talcum powders which will give consistent meaningful results.”²⁰⁸ It solicited “detailed procedures” on “the most promising approaches” to determine the presence of asbestos in talc.²⁰⁹

²⁰⁷ See Figure 4.

²⁰⁸ 1971.08.03 – DX7013 at 1.

²⁰⁹ 1971.08.03 – DX7013 at 6.

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127. Based on those discussions, the FDA began work internally to identify the most appropriate testing methods to use. It undertook “to collate and evaluate the various analytical procedures in use for the determination of asbestos in talc and other products, and to synthesize them into a package methodology which will give consistent, meaningful analytical results.”²¹⁰ Quarterly project progress reports from 1973 through 1977 discuss the FDA’s attempts to develop sufficiently sensitive and reliable methods.²¹¹

128. Within a year of the August 1972 meeting in which Dr. Lewin’s methods were seriously questioned, the FDA proposed an optical microscopy technique for the detection of asbestos in talc.²¹² Various companies attempted the method, including J&J, which found no asbestos in its Vermont talc by this method.²¹³ However, a “round robin” between the FDA and industry stakeholders, including the industry trade association, the CTFA, to test the method revealed it to be flawed, unworkable,²¹⁴ and “most importantly, totally unreliable.”²¹⁵ The participants reported widely inconsistent results using the FDA’s proposed method and raised their concerns with the FDA.²¹⁶ The CTFA “Talc Subcommittee” moved to “set up a task force to develop alternative methods,” which Dr. Rolle of J&J agreed to lead.²¹⁷ The task force collaborated on and set forth criteria for alternative testing methods developed and submitted by participants.²¹⁸ Dr. Rolle

²¹⁰ 1972.01.28 – FDA Internal Memorandum re: Asbestos Activities in the Bureau of Foods at 1.

²¹¹ See 1973.09.06 – DX8188.

²¹² See 38 Fed. Reg. 27076 (Sept. 28, 1973).

²¹³ See 1973.10.09 – DX8341.

²¹⁴ See 1973.10.11 – JNJ 000258078 at 079 (“It was agreed that we run a ‘round robin’ test... The following eight volunteered to test (or have tested) samples by optical microscopy (Fed. Reg. 9/28/73) and those designated by asterisk [included J&J] will also test by the X-ray diffraction step scanning method used by Colgate.”); 1973.12.10 – JNJ 000472232.

²¹⁵ 1976.03.18 – JNJ 000330509 at 509.

²¹⁶ See 1973.12.10 – JNJ 000472232.

²¹⁷ See 1973.12.07 – JNJ 000472240; 1973.12.11 – JNJ 000267300 at 301 (“The committee designated the formation of an ad-hoc CTFA subcommittee of Analytical Specialists which would be charged with the task of developing and proposing to the FDA a method acceptable to industry for the determination of asbestos in talc. Immediate representatives on this subcommittee would be derived from J&J, Colgate, Pfizer, and United Sierra. If required, this subcommittee is also empowered to add members from other CTFA Companies, from outside consultants, and from FDA. J&J representatives are Messrs. F.R. Rolle, D.H. Hamer, and J.P. Schelz. Dr. Rolle was designated as Chairman of this ad-hoc committee.”).

²¹⁸ See 1974.02.19 – JNJ 000258014 at 014 (“The methods must be applicable to finished products and must meet the following criteria: a) must be specific for detection of asbestos in talc and it, or a follow up method, must discriminate between fibrous and non-fibrous forms of asbestos. b) must have definable detection limits. c) must be reproducible among different workers with different instruments. d) must result in a pass or fail on a talc.”).

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solicited the participation of the FDA in the development of the method.²¹⁹ The FDA responded to the work of the task force with a revised proposal, but it did not reflect the input of the task force. Not surprisingly, the CTFA heavily criticized the FDA's revised proposal for being ineffective and time consuming, among other criticisms.²²⁰ Faced with universally negative feedback - from the CTFA and others -, the FDA decided to table its proposed implementation until a more acceptable method could be developed.²²¹

129. In light of the failure of the FDA's proposed optical method, the industry and the FDA subsequently worked together to develop an effective standard.²²² During an August 1974 meeting of the CTFA Talc Subcommittee, members noted the practical need for the FDA to propose universal regulation otherwise the "individual states would be making up their own" and cause "a lack of uniformity across the board."²²³ Those efforts culminated in the development of the CTFA J4-1 method for the detection of amphibole asbestos in cosmetic talc.²²⁴ The J4-1 method utilizes a two-step combination of x-ray diffraction,

²¹⁹ See 1974.03.13 – JNJ 000257893 at 893 ("Today I called Dr. John Stuart... Since he had indicated his willingness to work with the Task Force using his x-ray diffractometer and newly acquired differential thermal analysis equipment, my purpose in calling was to offer to get together with him to collaborate on our mutual efforts with those techniques. Dr. Stuart felt that a meeting would be of little value because he had been asked to devote all his time to utilizing the FDA optical microscopy method for examining the commercial talcum powders previously analyzed by Dr. Lewin... Dr. Stuart feels that the optical microscopy method has severe limitations, and he is frustrated by the attitude of the FDA in not allowing him to work with instrumental methods for the detection of asbestos in talc. He is interested in participating in the round robin which has been proposed by the CTFA Task Force but may not have the opportunity since he has no one to assist him.").

²²⁰ See 1974.05.20 – JNJ 000301021; 1974.06.12 – JNJ 000258040.

²²¹ See 40 Fed. Reg. 11865 (Mar. 14, 1975) ("[The Commissioner] recognizes that an effective compliance method must have greater utility and acceptance than indicated by the comments on the proposed method. The Commissioner has, therefore, decided to delay any final regulation for talc until an acceptable method for determining the presence of asbestos particles can be developed for this substance.").

²²² See June 4, 2020 Interview of Dr. John Hopkins, noting J&J's interactions with the CTFA and the FDA, including meeting roughly every three months with the FDA. See, e.g., 1974.07.17 – JNJ TALC000376349 at 351 ("Dr. Nashed has met with George Sandland of the CTFA in the recent weeks to brief him on J&J's proposed strategy of recommending DTA and X-ray Diffraction as methods in identification of Chrysotile and Tremolite to the FDA... Mr. Sandland has concurred with this approach and will seek its endorsement to the FDA through the CTFA. Dr. Rolle's CTFA Task Force has initiated round robin with these two methods... Messrs. Nashed, Rolle and Lee will be jointly responsible to prepare a draft following in the format of the FDA original proposal with appropriate substitutions and offer this to George Sandland for his use with FDA."); 1975.02.04 – JNJ 000308264 at 266 ("A CTFA Task Force comprised of Dr. Berdick, Dr. Estrin (CTFA), Mr. Lee, Dr. Rolle and Mr. Sandland will meet with Dr. Robert Schaffner, Mer. Eiermann and their designated personnel at FDA on Friday, February 7, 1975. It is planned to propose the 0.5 to 1.0% limit for each fibrous tremolite and chrysotile in cosmetic talc. Our CTFA Task Force developed methodology will be submitted in latest form as part of the proposal."); 1975.02.07 – JNJ 000261557 (CTFA Talc Task Force meeting minutes with FDA).

²²³ See 1974.08.14 – JNJ 000308103 at 106.

²²⁴ See 1976.10.07 – DX7131. More recently written standards recognize that the same combination of tools (XRD and PLM) can also be used to detect serpentine minerals, specifically chrysotile asbestos. See 2011.08.01 – JNJ 000382537 at 538; see also **Figure 1**.

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and if that detected any asbestos minerals, polarized light microscopy (“PLM”) and dispersion staining to determine whether any detected minerals are asbestiform.²²⁵ The CTFA then confirmed members’ ability to execute the method in another “round robin,” ultimately concluding “the CTFA methodology to be practical and basically sound.”²²⁶ While TEM was considered precise and capable of definitive mineral identification, it did “not lend itself to routine testing” by all industry participants as TEM required an expert operator and a sophisticated and expensive microscope that was beyond the means of some industry participants.²²⁷ The FDA would later conclude the CTFA J4-1 method “contributed to the continued improvement of cosmetic talc quality.”²²⁸

130. The establishment of testing methods was accompanied by discussions among industry participants and regulators over how to interpret the results of these tests. Dr. Eiermann of the FDA proposed “non-detectable” terminology for test results in which no asbestos was found. This was consistent with existing standards for measuring asbestos levels among mine workers.²²⁹ Similar terminology was added to the J4-1 standard, which adopted a “‘none detected’ limit for fibrous amphiboles.”²³⁰ Shortly after finalizing J4-1, Bill Ashton of J&J and Dr. Jerome Krause of CSMRI jointly presented a paper titled “Misidentification of Asbestos in Talc,” which discussed the x-ray diffraction and optical microscopy techniques that comprised the CTFA J4-1 method in “the hope that our guidelines will enable analysts to avoid the misidentification of asbestos in talcs” and that further explained how J4-1 was designed to identify asbestos if present.²³¹

²²⁵ See 1976.10.07 – DX7131. J&J combined the industry-standard J4-1 method, which addressed amphibole asbestos in particular, with both differential thermal analysis and transmission electron microscopy for the detection of serpentine minerals, specifically chrysotile. See **Figure 3**.

²²⁶ See 1977.02.01 – NJN 000026623 (“Dr. Estrin reported publication of a new CTFA Standard for talc and distributed copies to FDA. He described a round-robin test of cosmetic talcs which have been recently purchased on the open market. Participants in the round-robin test include scientists from Mt. Sinai Hospital and the Food and Drug Administration.”); 1977.03.31 – NJN 000250539 (CTFA method round robin); 1978.02.09 – NJN 000295353 (final re-test of the CTFA method).

²²⁷ See 1976.03.18 – NJN 000330509 at 510.

²²⁸ 1986.07.11 – DX7214 at 4.

²²⁹ See 1975.02.07 – NJN 000261557 at 559 (“Dr. Schaffner added the political inadvisability of citing mineworker standards for cosmetic talcs, and advised that it would be more meaningful to have animal studies with talc than statistical estimates. Mr. Lee responded by noting animal work in progress. Mr. Eiermann then proposed ‘non-detectable’ terminology rather than numerical limits.”).

²³⁰ See 1976.10.16 – NJN 000307321 at 321 (“The new Cosmetic Talc standard is a modification of the old TGA/CTFA Talc standard with the following major additions... 2. The addition of ‘none detected’ limit for fibrous amphiboles, using CTFA Method J4-1. A primary detection of amphiboles by X-ray diffraction is employed. When a positive detection of amphiboles is indicated, a secondary procedure using light microscopy along with dispersion staining is applied to determine whether or not the minerals detected by X-ray diffraction are asbestiform in nature.”).

²³¹ Krause & Ashton, “Misidentification of Asbestos in Talc,” *National Bureau of Standards*, Special Publication 506, November 1978, p. 351.

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**(2) Johnson & Johnson Implements Updated Testing
Methodology for Routine Testing and Quality Control**

131. When allegations of asbestos in cosmetic talc were raised by Dr. Langer and Dr. Lewin in the 1970s, J&J actively engaged in a sensemaking process with external stakeholders, as described above. While working with the FDA and the industry, J&J also dedicated time and resources to refining its own testing methodology which, in the end, was more rigorous than that adopted by the industry.
132. Internally, J&J responded with a significant commitment of resources devoted to monitor the quality and safety of its cosmetic talc. It tested each of its products,²³² each of its ore sources,²³³ and both current and historical samples of its baby powder²³⁴ to gain a complete perspective on any potential contamination with asbestos.²³⁵ J&J sought out opinions from, and sponsored studies performed by, independent experts, including experts from Massachusetts Institute of Technology, Princeton University, the Harvard School of Public Health, Carnegie-Mellon, University College-Cardiff, CSMRI, McCrone, Sperry Rand, the Atomic Energy Research Establishment at Harwell, the Mining Institute of Torino, Italy, and others.²³⁶ This testing confirmed for J&J that its talc was not contaminated with asbestos.²³⁷
133. J&J also initiated and subsequently expanded a routine testing program to test its Vermont talc for the presence of asbestiform minerals.²³⁸ The company updated its talc specifications to require an absence of asbestos after seeking input from experts such as

²³² See 1972.11.29 – DX7053 (Johnson’s Baby Powder testing); 1972.10.17 – DX8372 (Shower to Shower testing); 1973.11.09 – DX7078 (Medicated Powder testing). See also **Figure 3**.

²³³ See 1975.01.14 – DX7100 (Vermont talc testing); 1972.11.29 – DX7053 (Vermont talc testing); 1972.10.17 – DX8372 (Italian talc testing). See also **Figure 3**.

²³⁴ See, e.g., 1972.09.08 – DX7044 (Italian talc powders test dating back to 1949).

²³⁵ Wilson Nashed, on behalf of J&J, transparently articulated that J&J knew “of no process that guarantees total removal of all elongated particles from talc,” but firmly believed that its purification methods were “the most advanced in the field.” See 1972.10.11 – JNJ 000247766 at 766.

²³⁶ See, e.g., 1972.10.17 – DX8372; see also 1979 – DX8079; 1975.05.05 – WTALC00002531 (Letter from J. Dement, NIOSH, to V. Zeitz).

²³⁷ See 1979.01.11 – DX9199 at 3.

²³⁸ See 1972.03.20 – JNJ 000285265 (“At a meeting in January, it was decided to start examining Vermont Talc, on a weekly basis, for the presence of asbestiform minerals.”); see also 1971.08.13 – JNJ TALC000290227 at 227 (“Quality control should be upgraded and the possible presence of asbestos be determined on periodic samples.”).

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Walter McCrone.²³⁹ It adopted the industry-standard J4-1 method²⁴⁰ but also exceeded the industry standard by requiring routine TEM testing as well.²⁴¹

134. J&J gained its experiential knowledge with TEM using methods developed by McCrone. From the initial allegations of asbestos in cosmetic talc, McCrone shared its TEM expertise with J&J. A report dated August 10, 1971 from McCrone to J&J described the many methodologies for the determination of asbestos in talc, including TEM.²⁴² When J&J began revising its talc specifications to explicitly include asbestos testing, it turned to Walter McCrone for his expertise.²⁴³ In 1977, J&J internally adopted McCrone's TEM method for its routine testing program, which became known as TM7024.²⁴⁴

135. TM7024, which combined TEM to detect asbestiform minerals based on morphological characteristics and selected area electron diffraction for mineralogical identification, was highly sensitive.²⁴⁵ Further, the limit of detection was superior to that of J4-1 making "[t]hese techniques... currently the ultimate analytical tools for unequivocal determination of asbestos minerals in a talc matrix."²⁴⁶ It was the FDA's view that concerns over the misidentification of asbestos in talc, or about the detection limits of other methods, are resolved by the use of TEM. PLM, combined with TEM, continue to

²³⁹ See 1976.09.03 – JNJ 000273583.

²⁴⁰ See 1977.08.12 – DX7144 at 2 (Windsor 66 Specification).

²⁴¹ See 1978.02.23 – DX7147 at 1 (“[W]e need to recognize that Windsor Minerals and Johnson and Johnson have exercised more extensive controls and testing in the past than just meeting the J4-1 requirement. Furthermore, we intend continuing to surpass the industry testing as reflected by CTFA’s J4-1.”); see also 1977.04.29 – DX7141 (TM7024 Specification). J&J also routinely tested for serpentine minerals using differential thermal analysis. See 1977.06.28 – DX7143; 1977.04.05 – JNJ 000021787.

²⁴² See 1971.08.10 – DX7018 at 5-7.

²⁴³ See, e.g., 1976.09.03 – JNJ 000273583 (A proposed cosmetic talc specification containing handwritten comments by Walter McCrone).

²⁴⁴ Compare 1977.04.11 – JNJ 000311475 (Standard Test Method ADL-1305); 1977.04.29 – JNJ 000237206 (TM7024) with 1971.08.10 – DX7018 (Report by McCrone describing a similar TEM method). In 1990, after TEM had been used to analyze talc for more than fifteen years, Kremer and Millette published the TEM procedure used by McCrone for identifying and quantifying asbestiform minerals in talc in *The Microscope*, an international, peer-reviewed journal. 1990 – DX9666.

²⁴⁵ See 1977.04.29 – DX7141 at 2 (TM7024 Specification) (“This method is capable of detecting a single fiber in the entire TEM field, a negligible level in terms of weight percentage. TEM/SAED is an ideal technique when the asbestos fiber size is $\leq 0.2 \mu\text{m}$.”); See also 1990 – DX9666 at 10 (“This method can detect a single fiber as small as 1 micrometer (μm) long by $0.075 (\mu\text{m})$ wide in the entire TEM field, which results in a theoretical detection limit of 10^{-5} weight percent.”).

²⁴⁶ See 1977.04.29 – DX7141 at 1 (TM7024 Specification); See also 1990 – DX9666 at 10 (“This method can detect a single fiber as small as 1 micrometer (μm) long by $0.075 (\mu\text{m})$ wide in the entire TEM field, which results in a theoretical detection limit of 10^{-5} weight percent.”); This is compared to the 0.5% limit of detection capably by J4-1. See 1976.10.07 – DX7131.

be the most sensitive methods available today,²⁴⁷ and these methods were used by the FDA as part of its testing of talc-containing cosmetic products as recently as 2023.²⁴⁸

136. J&J's routine testing program imposed three layers of testing: biweekly composite samples of ground ore ("float feed"), weekly composite samples of dried talc ("milled powder"), and quarterly samples of finished talc, which were to be tested by a combination of XRD, PLM, and TEM.²⁴⁹ In later decades, J&J and/or its suppliers would expand to other nearby Vermont talc mines,²⁵⁰ including the Argonaut,²⁵¹ Rainbow,²⁵² and Hamm²⁵³ mines, and any "non-conformance to the specified Description/Properties & Requirements, [continued to] be cause for rejection."²⁵⁴

²⁴⁷ In a March 2019 statement, FDA Commissioner Scott Gottlieb described the PLM and TEM techniques used in a 2010 FDA survey of talc cosmetic products as "the most sensitive techniques available." *See* 2019.03.05 – DX8029; "2010 Talc Survey Appendix," *FDA*, available at <https://www.fda.gov/media/122418/download>.

²⁴⁸ *See, e.g.*, "FDA Summary of Results from Testing of Official Samples of Talc-Containing Cosmetics for Asbestiform Fibers Completed by AMA Laboratories in 2023," *FDA*, April 5, 2024, available at <https://www.fda.gov/cosmetics/cosmetic-ingredients/fda-summary-results-testing-official-samples-talc-containing-cosmetics-asbestiform-fibers-completed>.

²⁴⁹ *See* 1977.03.21 – DX7982; *see also* 1977.06.28 – DX7143; 1978.02.23 – DX7147; **Figure 3**.

²⁵⁰ *See* **Figure 2B**.

²⁵¹ *See* Undated – JNJ 000348019 ("In 1986 the Argonaut mine switched to open pit mining and was used in our products (at as much as 60% in a blend with Hammondsville) until 1991 when we switched to Hamm (Argonaut was then used at 10-20%)."); *see also* 1995.07.21 – JNJ 000348021 (noting expansion and re-utilization of Argonaut in 1995); 1995.07.18 – JNJ 000348023 (protocol for adopting a 100% Argonaut Talc product); 1995.04.11 – JNJ 000240673 (project timeline for January 1, 1996 launch of 100% Argonaut talc product).

²⁵² *See* 1989.05.22 – JNJ 000223445 (discussing 1989 limited introduction of Rainbow mine talc into cosmetic grades).

²⁵³ *See* Undated – JNJ 000240691 at 692 (noting "the complete transition to 'all-Hamm' ore in 1990"); *see also* 1994.03.16 – DX7371.

²⁵⁴ 1994.03.16 – DX7371 at 5. Although the specific compositing schedule changed over time, the three layers of testing continued even after J&J sold Windsor Minerals to a third party, Cyprus Industrial Minerals Corporation ("Cyprus"). *See, e.g.*, 1990.11.26 – DX7235 (Letter from McCrone to Cyprus Windsor Minerals: "Under your letter of authorization dated 02 November 1990, we received three (3) talc samples for asbestos analysis by transmission electron microscopy... Examination found no quantifiable amounts of asbestiform minerals."). *See also* 1992.01.21 – DX8723; 1992.01.21 – DX8069; 1994.01.10 – DX8411. As part of its efforts to gather new information and distribute knowledge it gained, J&J also implemented a worldwide talc monitoring program through which international affiliates could submit samples from their talc sources for evaluation. *See* 1975.07.23 – DX8535 at 7 ("The objective of the work is to assure the safety of our talcum powder products worldwide. It is aimed primarily at documenting freedom from asbestos of all talcs in use corporately."). *See also* 1976.08.31 – DX8536; 1976 – DX8537; 1977.01.12 – DX7721; 1977 – DX8538; 1979.01.31 – DX7151; 1979 – DX8539; 1979-1980 – DX8540; 1981 – DX8541; 1983.01.31 – DX7178; 1983 – DX8543; 1985.03.01 – DX7198; 1985 – DX8545; 1994.05.02 – DX7381; 1996.06 – DX7409; 1999.12 – DX7416.

137. I have reviewed decades of testing results from J&J's testing program that repeatedly and consistently showed that J&J's talc did not contain asbestos.²⁵⁵ These results have been validated by external stakeholders as well. For example, in 1976, J&J authorized its longtime lab, McCrone, to share the results of its TEM testing for J&J with the FDA.²⁵⁶ That same year, McCrone, wrote to the CTFA and remarked, "Since 1973 none of the talcs which we have examined and which have been identified to us as production materials have shown any detectable levels of either chrysotile or asbestiform amphibole."²⁵⁷ In 1979, the FDA concurred with that assessment: "One firm, Johnson & Johnson, has also done extensive testing for asbestiform particles in cosmetic-grade talc; all results to date have been negative."²⁵⁸ In 1987, McCrone again remarked to a prospective customer of Windsor Minerals, J&J's wholly-owned subsidiary overseeing the Windsor, Vermont talc operations: "Windsor's product is free of asbestos. That has always been our opinion and continues to be our opinion based on over 15 years of closely examining this product."²⁵⁹

b. Improved Testing Methods and Standards Make Sense of Earlier Ambiguities

138. Improved methods that emerged in the mid-1970s led to a reassessment of earlier allegations regarding the presence of asbestos in cosmetic talc. J&J actively worked with the industry, scientists, and regulators to make sense of these allegations, and continuously addressed any new information concerning the safety of cosmetic talc to improve its understanding and knowledge, as I describe below.

(1) Dr. Langer and Mount Sinai

139. With the benefit of improved detection technologies, there was additional follow up to the earlier studies by Dr. Langer and Dr. Lewin, which confirmed that earlier results identifying asbestos in talc were incorrect.²⁶⁰ By 1976, when the press had again raised

²⁵⁵ See **Appendix D**.

²⁵⁶ See 1976.03.12 – DX7577 (McCrone indicating that "[s]ubject to the approval of our clients, we are prepared to make available to the FDA, through CTFA, the results of these analyses."); 1976.05.24 – DX7694 (Windsor Minerals notifying McCrone that "[y]ou are hereby granted permission to disclose data resulting from your tests on our samples.").

²⁵⁷ 1976.03.12 – DX7577 at 2.

²⁵⁸ 1979.01.11 – DX9199 at 3; *see also* 1986.07.11 – DX7214 at 4 ("[CTFA J4-1] contributed to the continued improvement of cosmetic talc quality.").

²⁵⁹ 1987.05.21 – DX7216.

²⁶⁰ See, e.g., 1976.06.04 – DX7125. Even prior to the mid-1970s, McCrone re-examined samples that Dr. Langer previously said contained asbestos and found that these samples did not contain chrysotile. See 1971.09.03 – JNJ 000269814.

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the allegations of asbestos in some cosmetic talcs based on Mount Sinai's work,²⁶¹ the scientists of Mount Sinai had concluded that J&J's talc was safe. Dr. Langer published a peer-reviewed article with Dr. Irving Selikoff, Dr. Arthur Rohl, and other Mount Sinai scientists that ultimately found no asbestos in J&J's talc.²⁶²

140. In that paper, published in 1976, Dr. Langer and his colleagues at Mount Sinai reported the results of their testing of 21 baby powder products formulated prior to 1973 and reported that 10 samples contained detectable amounts of tremolite and/or anthophyllite, and two contained detectable amounts of chrysotile.²⁶³ Although none of the samples found to contain asbestos were J&J products, a March 10, 1976 *New York Times* article, "Asbestos Found in Ten Powders," included these results and suggested that talcum powder was unsafe.²⁶⁴

141. Due to the misleading reporting, on March 22, 1976, J&J employees met with Mount Sinai's president, Dr. Thomas Chalmers, to discuss the need for a statement correction about Dr. Langer's results and the safety of talcum powder.²⁶⁵ Dr. Chalmers agreed to write a cover note for the retraction statements,²⁶⁶ and, subsequently, Mount Sinai issued a statement to correct confusions about the reported asbestos content of some talcum powders.²⁶⁷ The statement affirmed that "[t]he most commonly used baby talc has been consistently free of asbestos.... It is the opinion of Mount Sinai's Department of Pediatrics that baby talc is a useful and safe product."²⁶⁸

142. The statement was discussed in a March 26, 1976 *Washington Post* article.²⁶⁹ In its correction, the *Washington Post* gave the impression of a possible disagreement between Mount Sinai laboratory personnel and Dr. Chalmers. The same day, Dr. Selikoff wrote to

²⁶¹ See 1976.03.08 – JNJ 000029534 (*The Washington Post*, "Asbestos Fibers Found in Baby Powder," March 8, 1976); 1976.03.26 – JNJ 000313307 (*The Washington Post*, "Talcum Study Clarified by N.Y. Hospital," March 26, 1976). The March 8, 1976 article led to J&J's continued involvement, even though asbestos was not found in its baby powder, in order that the public be kept "accurately informed" and not unnecessarily frightened. See 1976.03.15 – JNJ 000030487 at 489, 490. When *The Washington Post* published a subsequent story with Mount Sinai's response, J&J told Mount Sinai the story "[fell] far short of our mutual goal in reassuring consumers about the safety of present day talcum powders." 1976.03.26 – JNJ 000304381.

²⁶² See 1976 – DX8096; 1975.11.21 – DX8240 (identifying which samples were tested). See also 1976.03.10 – DX8402 (*New York Times* article discussing Dr. Langer's paper which found asbestos in other companies' talc products but not in J&J's talc).

²⁶³ See 1976 – DX8096 at 11-13. See also 1976.09.22 – JNJ 000300244.

²⁶⁴ See 1976.03.10 – DX8402.

²⁶⁵ See 1976.03.31 – JNJ TALC000169805.

²⁶⁶ See 1976.03.31 – JNJ TALC000169805. See also 1976.03.23 – DX7119.

²⁶⁷ See 1976.03.23 – DX7119.

²⁶⁸ 1976.03.23 – DX7119 at 3.

²⁶⁹ See 1976.03.26 – JNJ 000304381.

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the article's author indicating, "I specifically stated that I was in agreement with Dr. Chalmers, that I thought his statement was carefully and accurately written."²⁷⁰ Dr. Selikoff separately criticized the reporter for the "deliberate distortion" of his views, which effectively reaffirmed his agreement with Dr. Chalmers that J&J's talc was not contaminated with asbestos.²⁷¹

(2) Dr. Lewin and the FDA

143. In the mid-1970s, the FDA's Division of Cosmetics Technology ("DCST") conducted a re-test of Dr. Lewin's results using the improved detection methods.²⁷² The results of this analysis differed significantly from those produced by Dr. Lewin several years prior.²⁷³ In 1976, it issued a report of the final results from its own testing of Dr. Lewin's samples.²⁷⁴ The FDA detected no asbestos in any of J&J's products. Walter McCrone would later call Dr. Lewin's original results "grossly wrong."²⁷⁵

144. In conversations with multiple reporters in March 1976, Heinz Eiermann,²⁷⁶ Director of the DCST, noted that more than 70 samples were tested by the FDA for asbestos using DTA and optical microscopy, and "[n]one were found to contain Tremolite or Chrysotile."²⁷⁷ Additionally, McCrone analyzed six of the allegedly contaminated samples on behalf of the CTFA using TEM and verified the FDA's finding of no asbestos.²⁷⁸

145. Meanwhile, Dr. Lewin continued performing regular analysis of commercial baby powder products between 1975 and 1984. He did not identify any evidence of possible asbestos in these years of testing using XRD.²⁷⁹

146. Later, recognizing that "the analytical procedures for determining asbestos in talc were not fully developed" during the early 1970s, the FDA would say it considered this early

²⁷⁰ 1976.03.26 – DX8846.

²⁷¹ See 1976.03.26 – DX8846.

²⁷² See, e.g., 1975.02.24 – Letter from R. Schaffner (FDA) to H. Romer, (N.Y. Dept. of Health) re: Talc Testing Methods. During the same period, the CTFA also analyzed samples of Dr. Lewin's talcum powders under its new methodology. See 1975.10.09 – JNJALC000169028; 1975.12.29 – JNJ 000267097.

²⁷³ See 1976.01.07 – DX7113.

²⁷⁴ See 1976.01.07 – DX7113.

²⁷⁵ 1980 – DX9267 at 8.

²⁷⁶ See Undated – JNJALC000444671 (Heinz Eiermann was formerly an analytical chemist for J&J and was recognized as a "scientific leader" in the TGA Cosmetic Journal.).

²⁷⁷ See 1976.03.08 – DX7996. See also 1975.04.15 – JNJ 000277315; 1976.02.27 – DX8248; 1976.03.16 – DX8906.

²⁷⁸ See 1975.04.15 – JNJ 000277315 at 317; 1976.05.10 – DX8818.

²⁷⁹ See Blumenthal, Deborah, "A Dusting of Powder," *The New York Times*, October 28, 1984, available at <https://www.nytimes.com/1984/10/28/magazine/beauty-a-dusting-of-powder.html>, p. 2.

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testing, including that of Dr. Lewin, Dr. Langer, and others discussed above, to be of “questionable reliability.”²⁸⁰ Similarly, Dr. Robert Clifton of the U.S. Bureau of Mines authored a paper in 1984 entitled “What is Talc?,” in which he summarized the existing confusion among the industry, regulators, and scientists in general by stating that talc “is a victim of the imprecision of mineral terminology, which does not distinguish between the fibrous and nonfibrous varieties of several amphiboles... Talc is a victim of monitoring methods that are totally nonspecific and call each elongate particle of whatever origin a fiber and, by analogy, asbestos. Most especially talc is a victim of imprecise asbestos definitions, which allow the inclusion of most amphibole particles of some elongation in those definitions.”²⁸¹ Contemporaneous with Dr. Clifton’s paper, others documented the “confused associations” among regulations and medical literature to clarify which “actually relate[d] to nonasbestiform amphiboles and cancer of the lung.”²⁸² J&J’s participation in discussions with regulators, scientists, and industry stakeholders during this period was an important aspect of its sensemaking process.

c. Johnson & Johnson and the Scientific Community Expand Relevant Research and Respond to Questions Regarding the Safety of Cosmetic Talc

147. In the early 1970s, new scientific studies focused on cosmetic talc led to conflicting results, some of which influenced public opinion regarding its potential health effects. In response to this confusion, J&J actively sought external knowledge to inform its understanding of the potential health risks of its baby powder. J&J employees worked with scientists to conduct additional research, and follow up on related independent research. J&J began monthly research review meetings focused on baby powder in 1974.²⁸³ A 1975 internal memo stated that J&J’s philosophy on research after the disruptive events in the early 1970s had shifted to “a more anticipative approach,” even if it resulted in “the risk of revealing marginal data which may be difficult to deal with politically and/or scientifically.”²⁸⁴ J&J’s engagement with the scientific community demonstrates a continued and proactive response to the disruptive ambiguity, consistent with best practices in organizational sensemaking.

(1) Cosmetic Talc Miner/Miller Epidemiology

148. In its broader effort to follow the relevant science, J&J sought to codify scientific knowledge related to potential health effects of workplace exposure to talc by studying

²⁸⁰ See 1986.07.11 – DX7214 at 3; see also 1984.01.26 – JNJ TALC000224369.

²⁸¹ 1984 – JNJ 000224493 at 1.

²⁸² 1986 – JNJ TALC000216929 at 941-942.

²⁸³ 1974.05.06 – JNJ 000309191.

²⁸⁴ 1975.03.03 – JNJ 000244981 at 982.

individuals working in talc mines. Talc miners and millers are exposed to significantly greater dust levels than cosmetic talc users; by one assessment, talc miners and millers in an Italy talc mine were exposed to between 12,000 and 120,000 times the amount of talc as a baby in one year.²⁸⁵ While this was relevant to J&J's process for sourcing talc, it served as an informative starting point to investigate non-workplace exposure to talc as well.

149. In 1973, J&J originated a study into the health of workers in Italian talc mines by partnering with a "recognized authority in occupational disease investigations" and director of the University of Turin's Institute of Industrial Medicines, Dr. Giovanni Rubino.²⁸⁶ J&J considered Dr. Rubino to be "a meticulous worker concerned with obtaining unassailable facts and is himself not concerned with personal gain from the study."²⁸⁷ and "a sincere, distinguished and most capable medical scientist."²⁸⁸ J&J agreed to fund the study and provided tens of thousands of dollars in support.²⁸⁹ His first study, presented in 1974²⁹⁰ and published in 1976,²⁹¹ would ascertain the causes of death for a cohort of individuals who had worked at the Italian mine.²⁹² The study found no incidence of increased mortality among Italian talc miners and millers due to talc, including no increased risk of mesothelioma.²⁹³

150. Following that study, Dr. Rubino suggested a second study on the morbidity of the Italian talc workers.²⁹⁴ Discussing it internally, J&J acknowledged that Dr. Rubino had the freedom "to do any studies he wishes" and wished to be kept informed of its progress.²⁹⁵

²⁸⁵ See 1976.05.25 – WTALC00004147 at 150; see also Undated – JNJ 000325484 (estimating between a 1,000x and 13,500x safety factor for adults and infants over industrial exposures, respectively).

²⁸⁶ 1974.10.30 – DX8374 at 3; 1974.02.14 – DX8740; 1973.10.26 – JNJ 000233320 (J&J memo discussing the planning of the study).

²⁸⁷ 1974.02.14 – DX8740 at 2; see also 1974.10.30 – DX8374 at 2 (discussing a surprising observation as "a testimony to Rubino's veracity that he has been worrying about that unexpected relationship in his findings").

²⁸⁸ 1974.10.30 – DX8374 at 3.

²⁸⁹ See 1975.05.29 – JNJ 000274628; 1974.05.14 – JNJ 000270553. By today's academic standards, such funding would often have been disclosed on the face of the paper. However, this was less common in the 1970s. See Krinsky, Sheldon and L.S. Rothenberg, "Financial Interest and Its Disclosure in Scientific Publications," *JAMA*, Vol. 280, No. 3 (1998), available at <https://jamanetwork.com/journals/jama/article-abstract/187744>.

²⁹⁰ See 1974.10.30 – DX8374.

²⁹¹ See 1976 – DX9383.

²⁹² See 1974.02.14 – DX8740 at 1 ("Professor Rubino has identified 271 individuals who worked in the mine for more than one year and who have died. It is this cohort from which he will be conducting his initial research study to determine the cause of their death.").

²⁹³ See 1976 – DX9383 at 6-7.

²⁹⁴ See 1978.01.05 – DX8214.

²⁹⁵ 1978.01.05 – DX8214.

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In his updated morbidity study, Dr. Rubino compared the death rates of the Italian talc worker population against the national Italian male population death rates and found no relationship between Italian talc exposure and cancer.²⁹⁶ The results of Dr. Rubino's studies have been independently confirmed in follow-up studies in 2003,²⁹⁷ 2017,²⁹⁸ and 2021.²⁹⁹

151. At the same time, NIOSH and the Harvard School of Public Health approached various Vermont talc mining companies, including Windsor Minerals, about conducting an epidemiological study of Vermont talc workers and environmental study of the mines and mills.³⁰⁰ The NIOSH-led study assessed whether "exposure to respirable particles of the specific mineral talc lead[s] to the development of malignant or non-malignant respiratory disease" and attempted to identify "the health consequences of exposures to impure talc."³⁰¹ The results of the epidemiological study were published in 1979; there were no mesotheliomas reported among the Vermont talc miners and millers that could be definitively attributed to occupational talc exposure.³⁰²
152. In support of such an epidemiological study, NIOSH and the Harvard School of Public Health examined talc from J&J's Vermont talc mine for the presence of asbestos; testing by various methods "revealed no asbestos in the bulk samples."³⁰³ A preliminary report for the study purported to identify "[s]ingle chrysotile fibers" in air filter samples

²⁹⁶ See 1979 – DX9382. SRI (Stanford Research) requested information "relating to size/shape/distribution factors of Italian talc" for NIOSH's Talc Criteria Document because they considered Dr. Rubino's study to be "the only study of magnitude having substance for threshold limit purposes." J&J also acknowledged how years of helping NIOSH and SRI had led NIOSH and SRI to seek counsel from J&J. See also 1979.03.01 – JNJ 000086347. J&J considered a "comprehensive review of all J&J data on talc exposure" to be a top priority. See 1977 – JNJ 000231576.

²⁹⁷ See 2003 – DX9074 (Coggiola et al.).

²⁹⁸ See 2017.07 – DX9351 (Pira et al.).

²⁹⁹ See Ciocan, Catalina, et al., "Mortality in the cohort of talc miners and millers from Val Chisone, Northern Italy: 74 years of follow-up," *Environmental Research*, forthcoming in Vol. 203, (2022) (hereafter ("Ciocan et al. (2022)"). The Ciocan et al. (2022) study was made available online on August 11, 2021. See Ciocan, Catalina, et al., "Mortality in the cohort of talc miners and millers from Val Chisone, Northern Italy: 74 years of follow-up," *Elsevier Inc.*, 2021, available at <https://www.sciencedirect.com/science/article/abs/pii/S0013935121011592?via%3Dihub>.

³⁰⁰ 1975.05.05 – WTALC00002531 (Letter from J. Dement, NIOSH, to V. Zeitz); see also 1976.05.20 – BASF_EMTAL000002211; 1979 – DX8079 at 1, 2, 13.

³⁰¹ 1975.05.05 – WTALC00002531 at 532 (Letter from J. Dement, NIOSH, to V. Zeitz).

³⁰² See Selevan et al., "Mortality Patterns Among Miners and Millers of Non-Asbestiform Talc: Preliminary Report," *Journal of Environmental Pathology and Toxicology*, Vol. 2 (1979); see also 1979 – DX9397 (Conference Paper by Selevan & Dement published in *Dusts and Disease* (1979)).

³⁰³ 1979 – DX8079 at 1, 13.

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collected from workers,³⁰⁴ but this was confirmed to be background contamination.³⁰⁵ The published study confirmed no asbestos was found in the talc bulk samples.³⁰⁶

(2) Dr. Cramer's Study Alleges Association Between Talc and Ovarian Cancer

153. J&J also followed the research alleging an association between talc and ovarian cancer as concerns started emerging in the 1970s.³⁰⁷ Then, in July 1982, Dr. Daniel Cramer and others published a study indicating “some support for an association between talc and ovarian cancer hypothesized because of the similarity of ovarian cancer to mesotheliomas and the chemical relation of talc to asbestos, a known cause of mesotheliomas.”³⁰⁸

However, the authors’ discussion was not conclusive with respect to causality, noting that “[i]f talc is involved in the etiology of ovarian cancer, it is not clear whether this derives from the asbestos content of talc or from the uniqueness of the ovary which might make it susceptible to carcinogenesis from both talc and other particulates.”³⁰⁹

154. In August 1982, J&J met with Dr. Cramer “to discuss [his] paper on the relation between perineal talc usage and ovarian cancer.”³¹⁰ J&J presented Dr. Cramer with a binder of studies and noted that the body of work did not show evidence of carcinogenic potential for talc.³¹¹ Dr. Cramer stood by his conclusions but admitted to certain flaws in his study and agreed that he would also abide by the interpretation of the American College of Gynecologists if it were to review the data and reach a different conclusion.³¹² Despite the apparent flaws in Dr. Cramer’s study, J&J publicly agreed that “more study is needed, and we are going to conduct appropriate new studies.”³¹³ J&J also kept apprised of other research regarding the alleged link between talc usage and ovarian cancer, including a 1983 examination by a team of doctors from the National Institute of Health and George Washington University that found “no overall association between talc use and the risk of ovarian cancer.”³¹⁴

³⁰⁴ 1977.08.10 – BASF_EMTAL000002244 at 2262.

³⁰⁵ See 1976.05.20 – BASF_EMTAL000002211 at 213.

³⁰⁶ See 1979 – DX8079 at 1, 13.

³⁰⁷ See, e.g., 1975.01 – DX8264 at 6 (noting the Tenovus study related to talc and “[c]ancer in ovaries”).

³⁰⁸ See 1982.07.15 – JNJ 000020733 at 733.

³⁰⁹ See 1982.07.15 – JNJ 000020733 at 737.

³¹⁰ See 1982.08.12 – JNJ 000029640 at 640.

³¹¹ See 1982.08.12 – JNJ 000029640 at 640.

³¹² See 1982.08.12 – JNJ 000029640 at 641.

³¹³ See 1982.08.12 – JNJ 000050448 at 448.

³¹⁴ 1984.04.11 – JNJ 000031294 at 304.

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155. Later in 1985, an FDA Quantitative Risk Assessment Committee reported to the W. Gary Flamm, Director of the Office of Toxicological Sciences, that the Cramer et al. study appeared to have been “misinterpreted statistically,” was not corrected “for several likely biasing factors,” and was “strongly contradicted by another study showing a reduced relative risk as significant in the negative direction as the Cramer study was in the positive direction.”³¹⁵ The committee concluded that “there appears to be no association between customary human talc use per se and ovarian cancer.”³¹⁶
156. As Dr. Nicholson testified,³¹⁷ J&J continued to closely follow the scientific research related to alleged associations between talc and ovarian cancer in the years following Dr. Cramer’s study. For example, in 1989, Dr. Semple of J&J noted that “we know of no scientific evidence that cosmetic talc causes cancer of any kind in animals or man,” which was also reinforced by the World Health Organization’s International Agency for Research on Cancer “after extensive review of the vast scientific literature on talc.”³¹⁸ Dr. Semple further described how research conducted by doctors from the National Institutes of Health and George Washington University “conducted research similar to Dr. Cramer’s that yielded results contradictory to his findings.”³¹⁹
157. J&J continued to closely follow this research over decades. For example, J&J employees participated in a 1994 workshop co-sponsored by the FDA and the International Society of Regulatory Toxicology and Pharmacology where the possible association between talc exposure and ovarian cancer was discussed.³²⁰ Additionally, in an internal public relations document from 1997, J&J noted that “a full FDA review of all of the research available” showed “no causal link between talc and ovarian cancer.”³²¹ In March 2020, J&J developed a “briefing document” summarizing “the general use and safety of talc” as well as “relevant data related to talc toxicology, lung effects, data related to ovarian cancer, and post marketing safety.”³²² With respect to research related to ovarian cancer, J&J conducted a “systematic review of the published literature [...] to identify epidemiologic studies of talc use and ovarian cancer in humans,” and summarized 47

³¹⁵ See 1985.06.06 – DX7201 at 6.

³¹⁶ See 1985.06.06 – DX7201 at 9.

³¹⁷ See Deposition of Susan Nicholson, M.D., November 18, 2020 (“Q. You agree that Johnson & Johnson has obviously followed this issue [the connection between ovarian cancer and Baby Powder] very closely, correct? A. Correct.”).

³¹⁸ See 1989.05.11 – JNJ 000022679 at 680.

³¹⁹ See 1989.05.11 – JNJ 000022679 at 680.

³²⁰ See 1995 – DX9060; see also 1995.08.15 – JNJ 000030833.

³²¹ See 1997.10.20 – JNJ 000024495 at 495.

³²² 2020.04.01 – JNJTALC001465273 at 286.

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relevant studies.³²³ J&J concluded from this review that “[o]n balance, given the more than 47 years of research available on talc use and ovarian cancer, comprehensive consideration of all the available data supports that talc does not cause ovarian cancer.”³²⁴

(3) Johnson & Johnson’s Proactive Engagement with the Scientific Community Regarding the Safety of Johnson’s Baby Powder

158. I also reviewed documents demonstrating J&J’s active engagement with other allegations of asbestos contamination over decades. Some of the allegations J&J has investigated and responded to were based on test results that reported finding talc of a certain shape, or amphiboles or serpentines which were not identified as asbestiform.³²⁵ Other results were attributed to outside contamination,³²⁶ or could not be verified.³²⁷ Other tests involved samples of talc that were not used in Johnson’s Baby Powder,³²⁸ were not a J&J product,³²⁹ or had no identifiable source.³³⁰ Still other documents merely made reference to asbestos, but were not test results.³³¹

159. The record further describes how J&J engaged proactively to understand and investigate more recent allegations. For example, in 1991, Alice Blount published a paper on her method for concentrating talc samples prior to analysis, using cosmetic and pharmaceutical grade talcs.^{332, 333} The paper reported finding needles and fibers in Sample

³²³ 2020.04.01 – JNJ TALC001465273 at 370-371 (“The sections that follow summarize results from studies concerning ovarian cancer from three prospective studies, 27 case-control studies, six meta-analyses, and 11 pooled case-control studies.”).

³²⁴ 2020.04.01 – JNJ TALC001465273 at 495. J&J further noted that “these conclusions have also been confirmed by the CIR Expert Panel [21], in addition to independent comprehensive reviews by NCI Physician Desk Query (PDQ) [82] and US FDA [64], among others.” See 2020.04.01 – JNJ TALC001465273 at 495.

³²⁵ See, e.g., 1958.05.23 – DX8383 (noting the presence of “tremolite” and “fibrous talc” in Italian No. 1 and No. 2 talcs).

³²⁶ See, e.g., 1978.10.05 – JNJ 000063169 (noting possible contamination from outside sources such as water or air).

³²⁷ See, e.g., 1997.12.04 – DX8678 (result could not be confirmed). See also 1998.01.21 – DX8680.

³²⁸ See, e.g., 1974.04.24 – JNJ 000222859 (discussing possible contamination in 1974 Argonaut ore body samples that were not used for cosmetic products until 1986). See also **Figure 2B**.

³²⁹ See, e.g., 1967.01.30 – JNJ 000235800 (another company’s product).

³³⁰ See, e.g., 1975.02.19 – JNJ 000065678 (unidentified sample).

³³¹ See, e.g., Undated – DX7835 (marketing document for Italian talc which implied the presence of “chrysotiles” and “tremolites”).

³³² See Blount, A.M., “Amphibole Content of Cosmetic and Pharmaceutical Talcs,” *Journal of Environmental Health Perspectives*, Vol. 94 (1991) p. 225.

³³³ Dr. Blount’s description of her concentration technique is consistent with J&J and others’ view of this type of technique as a sample preparation technique. This concentration technique alone cannot identify asbestos,

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I but did not further identify the sample.³³⁴ In subsequent J&J correspondence, and in documents produced during litigation, “sample keys” purported to identify Sample I as a J&J talc, although the keys are inconsistent with the paper’s description of the origins of the talcs analyzed.³³⁵ Recent testimony from Dr. Blount also revealed that she currently does not know the identity of Sample I.³³⁶ Dr. Blount was also asked by J&J if the sample was available for additional testing to resolve the confusion, and it was not.³³⁷

160. J&J’s active engagement with these allegations, and the scientific testing on which they are based, demonstrates an ongoing commitment to sensemaking and a willingness by J&J to revise its “map” if any of these allegations were disconfirming of its current understanding regarding the potential for asbestos in its baby powder.

d. Conclusion

161. In the context of sensemaking, J&J’s actions following the disruptive ambiguity of the early 1970s were focused on refining and codifying a new “map.” The new “map” resulted from J&J’s active involvement in, and commitment to, a sensemaking process, as well as its active engagement with regulators and scientists. The new “map” codified J&J’s understanding of the potential health risks associated with exposure to asbestos and talc and the safety of its baby powder. The new “map” was grounded in the new testing methods and new scientific knowledge that emerged during this time. Creation of this new “map” resolved much of the earlier ambiguity. In my opinion, J&J’s actions following the disruptive ambiguity of the early 1970s are consistent with an organization that seeks to challenge, and strengthen, its understandings through active engagement in sensemaking. This active engagement also strengthened J&J’s organizational capabilities

but rather requires subsequent testing methods to identify asbestos after the sample preparation. *See* Blount Deposition (2018) at 66:7-18. Further, it could not be universally applied to all types of asbestos, as Dr. Blount testified that her concentration method was designed to test for amphiboles, and that recalibration would be necessary to test for chrysotile asbestos. *See* Blount Deposition (2018) at 81:24-82:18. Assuming the heavy density separation is calibrated accurately, Dr. Blount acknowledged that it still matters what subsequent methods you use to identify asbestos. *See* Blount Deposition (2018) at 67:15-69:2.

³³⁴ *See* Blount, A.M., “Amphibole Content of Cosmetic and Pharmaceutical Talcs,” *Journal of Environmental Health Perspectives*, Vol. 94 (1991), pp. 225, 228.

³³⁵ *See* 1991 – JNJ 000379224 and 1991 – JNJ 000241177 (identifying only three international talcs despite the paper’s description that “four talcs from outside the U.S.” were analyzed); *Compare* 1998.04.23 – DX8380 (Letter from A. Blount to J&J claiming sample I in her prior 1990 paper is a J&J talc) with 1990 – DX9955 at 13 (finding no fibers in Sample I by “traditional” methods). *See also* Deposition of Alice M Blount, Ph.D., April 13, 2018 (hereafter “Blount Deposition (2018)”) at 100:6-8 (“[A. ...] Unfortunately, I didn’t make a good enough record, and I think some of [the samples] got a little mixed up.”).

³³⁶ *See* Blount Deposition (2018) at 47:15-48:5, 53:10-21, 101:2-6 (claiming she purchased Sample I in 1996 and, therefore, Sample I in her 1991 paper probably would not be J&J’s talc).

³³⁷ *See* Blount Deposition (2018) at 57:7:10.

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and commitment to a sensemaking process, and through that, its ability to anticipate and respond to future disruptions.

4. Johnson & Johnson Applies the “Map” Developed in Prior Decades to Regularly Evaluate, Update, and Disseminate Scientific Knowledge Regarding the Safety of Cosmetic Talc

162. Despite J&J codifying new knowledge regarding the potential for asbestos in cosmetic talc and talc safety, and disseminating this “map” throughout the organization, this codification was not static. J&J continued to attend to signals about the safety of baby powder, even after much of the disruptive ambiguity from the early 1970s had been resolved and its new “map” had been codified. The organization applied its “map” and its sensemaking capabilities to quickly investigate and respond to new allegations and ambiguities that arose, and to continue to engage with regulators and the scientific community to regularly update its “map.”

a. The FDA Rejects Asbestos Warning and Ovarian Cancer Warning for Talc

163. Following the controversy of the 1970s, the FDA received a Citizen Petition in November 1983 which requested an “asbestos warning statement” be placed on cosmetic talc-containing products.³³⁸ The Citizen Petition alleged that talc mining “almost invariably” includes mining asbestos as well, and that asbestos in cosmetic talc poses an “inhalation hazard” to humans.³³⁹

164. In 1986, after researching the issue further, the FDA denied the Citizen Petition.³⁴⁰ It rejected the petitioner’s argument that cosmetic talc products are contaminated with asbestos and noted that “most of the analytical work [cited] was conducted without scientific agreement as to which methods were well-suited for the identification of asbestiform minerals in talc. Consequently, the FDA considered all analytical results [from the early 1970s] to be of questionable reliability.”³⁴¹ The agency also noted that its own surveillance activities performed in the late 1970s showed that “the quality of cosmetic talc had significantly improved,” and concluded that “the risk from a worst-case estimate of exposure to asbestos from cosmetic talc would be less than the risk from environmental background levels of exposure to asbestos (non-occupational exposure) over a lifetime.”³⁴²

³³⁸ See 1986.07.11 – DX7214 at 3.

³³⁹ See 1986.07.11 – DX7214 at 3.

³⁴⁰ See 1986.07.11 – DX7214.

³⁴¹ See 1986.07.11 – DX7214 at 3.

³⁴² See 1986.07.11 – DX7214 at 4.

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165. In November 1994, the FDA received a Citizen Petition from the Cancer Prevention Coalition, which requested that cosmetic talcum powder products add labels such as “Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer.”³⁴³ Later in May 2008, the FDA received another Citizen Petition from the Cancer Prevention Coalition requesting that cosmetic talcum powder products add labels such as “Frequent talc application in the female genital area is responsible for major risks of ovarian cancer.”³⁴⁴ In April 2014, the FDA responded to both petitions noting that it “did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer” and further that it “did not find enough additional support at this point in time for your suggested warning label,” despite having reviewed additional scientific literature not cited in the Citizen Petitions.³⁴⁵ The FDA further stated that although there is potential for particulates to migrate to the peritoneal cavity, “there exists no direct proof of talc and ovarian carcinogenesis” and “there has been no conclusive evidence to support causality.”³⁴⁶

b. Johnson & Johnson Works with Regulators to Codify Existing Knowledge Regarding the Safety of Talc

166. As part of its ongoing commitment to sensemaking, J&J has continued to collaborate with industry regulators, and has continued its cooperative effort to ensure that standards for talc and detection methods for asbestos are consistent with current scientific knowledge. Since the 1970s, regulatory agencies, also in response to newly published studies and perceived public concern, have periodically conducted investigations into cosmetic talc products and engaged in discussions with the industry and consumers. I describe certain of these scientific and regulatory investigations, and J&J’s involvement in them, below.³⁴⁷ My understanding, from the review of the record, is that none of the regulatory standards have been revised in ways that disrupt J&J’s “map” of the relevant scientific knowledge.³⁴⁸

³⁴³ See 1994.11.17 – BCAL-BAILEY-00000503 at 504.

³⁴⁴ See 2008.05.13 – BCAL-BAILEY-00000519 at 520.

³⁴⁵ See 2008.05.13 – BCAL-BAILEY-00000572 at 572 and 575.

³⁴⁶ See 2008.05.13 – BCAL-BAILEY-00000572 at 576.

³⁴⁷ J&J also received and discussed scientific research as part of the Talc Interested Party Task Force of the CTFA. See, e.g., 1993.04.05 – JNJ 000373736 and 1995.03.28 – JNJ TALC001243445.

³⁴⁸ I note that in 1990 NIOSH commented on OSHA’s notice of proposed rulemaking on occupational exposure to asbestos, suggesting to not distinguish between asbestiform and non-asbestiform tremolite, anthophyllite, and actinolite. However, as noted in **Figure 4**, NIOSH later reversed their opinion in 2011.

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(1) NTP and IARC

167. In the early 2000s, the NTP revisited the issue of talc carcinogenicity and conducted a review that considered whether to list talc as a carcinogen in its Report on Carcinogens. Notably, the NTP indicated that it invited collaboration in this process. For example, during a 1999 public meeting, the NTP director, Dr. Kenneth Olden, acknowledged the possibility that the program could make a mistake and stressed that the NTP valued public input.³⁴⁹ In announcing its intent to review 21 nominations, including talc, for possible listings in its 12th *Report on Carcinogens*, the NTP asked for “public input” and “relevant information concerning their carcinogenesis” while also “invit[ing] interested parties to identify any scientific issues related to the listing of a specific nomination in the [Report on Carcinogens] that they feel should be addressed during the reviews.”³⁵⁰

168. Therefore, J&J, like other companies, was afforded the opportunity to participate in the process.³⁵¹ Testimony from J&J personnel indicates that J&J participated in the public comment process and communicated with the NTP in the interest of sharing its knowledge and its understanding of the science. Steven Mann, a director of toxicology at J&J, explained that “agencies have specific public comment periods where they invite information, submissions from the public, from corporations,” and that J&J worked to

³⁴⁹ National Toxicology Program, Public Meeting of the Report on Carcinogens, October 22, 1999, pp. 144-145 (“So, clearly the process involves transparency, public input and peer review. So, that’s why we instituted so clearly, we value public input, quality peer review and scientific rigor. ... I think it’s important to have peer review, because that clearly this report not only could have significant impact on human health, but it could have significant impact on the economy. ... [W]e, government scientists are not empowered, but we could make a mistake.”).

³⁵⁰ 2004.05.19 – JN JNL61_000105443 at 445. *See also* National Toxicology Program; Call for Public Comments on Substances, Mixtures and Exposure Circumstances Proposed for Listing in the Report on Carcinogens, Tenth Edition, 65 Fed. Reg. 17889 (April 5, 2000) at 17890 (“The NTP is considering 11 agents, substances, mixtures and exposure circumstances for possible review in 2000, as either a new listing in or changing the current listing from reasonably anticipated to be a human carcinogen to the known to be a human carcinogen category in the Tenth Report... The NTP solicits public input on these 11 nominations and asks for relevant information anyone may have concerning their carcinogenesis, as well as current production data, use patterns, or human exposure information. The NTP also invites interested parties to identify any scientific issues related to the listing of a specific nomination in the RoC that they feel should be addressed during the reviews.”); National Toxicology Program; National Toxicology Program (NTP) Board of Scientific Counselors’ Meeting; Review of Nominations for Listing in the 10th Report on Carcinogens, 65 Fed. Reg. 61352 (October 17, 2000) at 61353-61354 (“The NTP Board of Scientific Counselors RoC Subcommittee meeting is open to the public, and time will be provided for public comment on each of the nominations under review. ... Written comments, in lieu of making oral comments, are welcome. ... Solicitation of Additional Information: The NTP would welcome receiving information from completed human or experimental animal cancer studies or studies of mechanism of cancer formation, as well as current production data, human exposure information, and use patterns for any of the nominations listed in this announcement.”).

³⁵¹ *See, e.g.*, 2005.01.06 – JNJ 000369221 at 222 (In a November 2004 letter to the Director of the National Institutes of Health, the administrator of the Office of Management and Budget noted: “The Report on Carcinogens already acknowledges that ‘opportunities for public comment and participation are an integral part of the review process.’”).

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“get all the science that [J&J] had, organize it, review it and give [the NTP] a summary during the public comment period.”³⁵² Dr. Mann further testified that the comment period was J&J’s opportunity to pull together all of the literature, including relevant studies, in one place to ensure that the NTP had “the full literature to make their decisions.”³⁵³ Joan Casalvieri, director of toxicology and Dr. Mann’s supervisor, corroborated this testimony and described that Dr. Mann’s goal was to “make sure that the NTP had all the right information, which was in the public domain, to be included in their considerations and with the understanding that [J&J] wanted them to come to an independent decision, but based on all the data that – that should be reviewed.”³⁵⁴

169. In response to NTP’s review of talc as a potential carcinogen, Rich Zazenski of Luzenac enlisted the help of the Center for Regulatory Effectiveness (“CRE”) to demonstrate to the NTP why it was incorrect to list talc as a carcinogen.³⁵⁵ The CRE identified three “fatal flaws” in the NTP proposal, and in the end, talc was withdrawn from consideration

³⁵² Deposition of Steven W. Mann, February 17, 2022 (hereafter, “Mann 2022.02.17 Deposition”), pp. 96, 104. *See also* Deposition of Steven Mann, Volume II, February 19, 2021 (hereafter, “Mann 2021.02.19 Deposition”), pp. 436-437 (“Q. How did you understand the opportunity for public comment to work as it relates to the NTP? A. That they have a period when you can submit documents, papers, whatever you think that they should have on substances that have been nominated. Q. And what was the purpose of interested parties submitting comments as you understood it during the time period that you worked there? ... A. So that they would have a full -- would have all the scientific information they would need for their review.”); Mann 2022.02.17 Deposition, pp. 100-101 (“A. ... [I]t’s best to ... be more cooperative with the agencies, rather than antagonistic, so basically to work with them, to get them information, to write a summary of what you think this means and let them do their job.”).

³⁵³ Mann 2022.02.17 Deposition, pp. 118-119 (“Q. What do you believe the objective was? A. To get all of the science to them as best -- that is out there. So in the case of a -- of a major review, the -- the value of that is that it brings together in one place all of the relevant studies and discusses them and, you know, looks at the whole big picture so that, you know, you -- that’s one -- one good way to get all the information in one place with some discussion, rather than expecting the NTP to go find all these things on their own because we’d had difficulty before where they were missing things. So this is our opportunity through the comment period to pull together the literature and -- and -- and, yes, we believe it will support it, but that’s not -- that’s not the -- the purpose. The purpose is to get all the science there, whatever that science is, so that they have the full literature to make their decisions on.”).

³⁵⁴ Deposition of Joan Casalvieri, February 15, 2022 (hereafter, “Casalvieri 2022.02.15 Deposition”), p. 93. *See also* Casalvieri 2022.02.15 Deposition, pp. 94-95 (“The purpose of his work was to make sure that all the right information would be considered in that review. [...] The purpose of that work was to make sure that the NTP came to a scientifically valid conclusion. [...] [J&J] wanted to make sure that the NTP had considered an inclusive body of information to come to their decision. Whatever their decision was, [J&J] wanted an independent decision, and [J&J] would have done whatever the appropriate reaction would have been.”).

³⁵⁵ *See, e.g.*, 2000.11.27 – JNJ 000238358 (“For now, I’ll graciously accept 100% of the credit 1) finding CRE, 2)[]convincing them to get involved, 3) developing the Fatal-Flaw Strategy. 4) single-handedly saving the talc business from certain ruin. All in a day’s work. All contributions to the RJZ vacation and retirement fund will be accepted.”).

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for inclusion on the carcinogenic listing.³⁵⁶ NTP meeting minutes from December 2000 indicate scientific uncertainty among NTP subcommittee members following presentations at the December 2000 meeting of the NTP Board of Scientific Counselors Report on Carcinogens Subcommittee, but not as a direct result of J&J's actions.³⁵⁷ The minutes from this December 2000 meeting clearly demonstrate that confusion existed prior to the meeting's public comment period. For example, the minutes indicate that Subcommittee member Dr. Michele Medinsky "said that listing talc in the *Report* is not a straightforward issue, and this was before she heard all the comments made in this meeting" and shared her uncertainty about talc's alleged association with ovarian cancer before ultimately saying that she would not support the listing of talc.³⁵⁸

170. Leading up to NTP's decision to defer consideration of the listing of talc, an email produced by Imerys, which acquired Luzenac to become J&J's sole U.S. talc provider in 2011, states "[t]ime to come up with more confusion" regarding NTP's review of talc. However, it is important to highlight that this statement was made by Robert Bernstein to Rich Zazenski (both Luzenac employees) within an internal email chain amongst *only* Luzenac employees.³⁵⁹ This perspective, therefore, cannot be attributed to J&J. Steven Mann's (J&J) testimony clarifies that Luzenac employee Rich Zazenski tended to "boast" and be "very aggressive" in his language, and Dr. Mann stated that "I [did not] act on what he says."³⁶⁰ For example, Mr. Zazenski's aggressive and boastful language is reflected in an email in which he "accepts 100% of the credit" for the "Winning Hand" in

³⁵⁶ See, e.g., 2000.11.29 - IMERYYS 100151 at 153-154; see also "Talc Removed From 12th RoC," *HBW Insight*, October 24, 2005, available at <https://hbw.pharmaintelligence.informa.com/RS013458/Talc-removed-from-12th-RoC>.

³⁵⁷ Summary Minutes of the National Toxicology Program Board of Scientific Counselors Report on Carcinogens Subcommittee Meeting, December 13-15, 2000.

³⁵⁸ Summary Minutes of the National Toxicology Program Board of Scientific Counselors Report on Carcinogens Subcommittee Meeting, December 13-15, 2000, p. 17.

³⁵⁹ 2001.01.04 – IMERYYS-A_0024290.

³⁶⁰ See Deposition of Steven Mann, Volume I, February 15, 2021, pp. 250-251 ("Q. Do you have any evidence that you wrote any e-mail back to Mr. Zazenski opposing what he says here? [...] A. I don't recall. He was always very robust to boast or whatever. [...] Q. And you said that no one suggested to you that political pressure be applied to IARC; that's exactly what's being suggested in this e-mail, correct? [...] A. Yes, Rich can boast and I'm not doing that."). See also Deposition of Steven Mann, Ph.D., Volume II, April 28, 2021 (hereafter, "Mann 2021.04.28 Deposition"), pp. 393-394 ("Q. Okay. Tell us your impression of Mr. Zazenski? A. Well, he was -- worked for Luzenac and, yeah, he was sometimes, in my opinion, very aggressive with his speculation about things or his ideas of what, you know, should or should not be a proper response, but I take his words with a minimum of -- I don't act on what he says."); Mann 2021.04.28 Deposition, p. 433 ("Q. Okay. And when the corporation lawyer asked you questions, you said: I didn't have any intelligence. That was Rich Zazenski talking, and that he uses aggressive words. [...] Q. Do you recall that, Doctor? A. Yes, I recall answering the question.").

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front of the NTP.³⁶¹ While Steven Mann credited J&J's "efforts in coordination with Luzenac and CTFA,"³⁶² he also testified that J&J's posture towards the NTP was to make sure that the NTP had "an inclusive body of information" that it could rely on to come to an independent decision.³⁶³

171. Following the NTP's decision to defer consideration of the listing of talc in July 2001, Dr. Olden thanked participants for their comments and noted that the NTP "would welcome any information" to clarify issues identified during its review of talc.³⁶⁴ In response, J&J expressed interest in working more closely with the NTP, with personnel believing that "an industry / NTP working group would provide an excellent educational forum to address NTP knowledge deficits in a proactive way."³⁶⁵

172. For example, J&J assisted in an updated review of the literature that provided the NTP with 90 publications, including more than 50 that had not been referenced in the NTP's draft background document, in order to "mak[e] sure that the NTP ha[d] all of the available science."³⁶⁶ Notably, the CTFA indicated that this submission was "in response to the offer of collaboration" extended by the NTP.³⁶⁷ Following this review, J&J performed another full literature search in 2004 when the NTP reconsidered talc. This included searching for "all published papers, technical, safety, patents, medical, clinical

³⁶¹ See 2000.11.27 – JNJ 000238358 ("For now, I'll graciously accept 100% of the credit 1) finding CRE, 2)[] convincing them to get involved, 3) developing the Fatal-Flaw Strategy. 4) single-handedly saving the talc business from certain ruin. All in a day's work. All contributions to the RJZ vacation and retirement fund will be accepted.").

³⁶² See 2005.10.19 – JNJ 000369269 at 270.

³⁶³ See, e.g., Mann 2022.02.17 Deposition, pp. 118-119 ("Q. What do you believe the objective was? A. To get all of the science to them as best -- that is out there. So in the case of a -- of a major review, the -- the value of that is that it brings together in one place all of the relevant studies and discusses them and, you know, looks at the whole big picture so that, you know, you -- that's one -- one good way to get all the information in one place with some discussion, rather than expecting the NTP to go find all these things on their own because we'd had difficulty before where they were missing things. So this is our opportunity through the comment period to pull together the literature and -- and -- and, yes, we believe it will support it, but that's not -- that's not the -- the purpose. The purpose is to get all the science there, whatever that science is, so that they have the full literature to make their decisions on."); Casavieri 2022.02.15 Deposition, pp. 94-95 ("The purpose of [Mann's] work was to make sure that all the right information would be considered in that review. [...] The purpose of that work was to make sure that the NTP came to a scientifically valid conclusion. [...] [J&J] wanted to make sure that the NTP had considered an inclusive body of information to come to their decision. Whatever their decision was, [J&J] wanted an independent decision, and [J&J] would have done whatever the appropriate reaction would have been.").

³⁶⁴ 2001.07.09 – IMERYYS 061699. See also 2001.07.17 – JNJ 000564650 at 651 ("Ken [Olden, Director of NTP] welcomes the participation of the industry in defining a suitable category for review and in identifying specific research projects that would provide clarity to these issues.").

³⁶⁵ 2001.07.17 – JNJ 000564650 at 650. See also 2001.08.16 – JNJNL61_000091891 ("It was unanimous among the task force members that CTFA should work with NTP as it continues to do the review of Talc.").

³⁶⁶ Mann 2021.02.19 Deposition, p. 377.

³⁶⁷ 2002.03.18 – JNJ TALC000109268 at 268.

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with regard to talc starting with Jan 1 2000 through current date,” with a particular interest in “any literature related to ovarian cancer,” in order to “make sure that [the talc] literature review [wa]s up to date.”³⁶⁸ Importantly, as Dr. Casalvieri conveyed, while there was “nothing J&J could directly do to prevent classification” of talc as a carcinogen by the NTP, the company “wanted the NTP to have all the pertinent information so they could make the right decision.”³⁶⁹

173. Similarly, in 2010, IARC published a new monograph that evaluated the carcinogenic hazards of “talc not containing asbestiform fibres” and listed perineal use of talc-based body powder in Group 2B (possibly carcinogenic) and inhaled talc not containing asbestos or asbestiform fibres in Group 3 (not classifiable as to its carcinogenicity).³⁷⁰ The monograph provides an exhaustive review of the existing scientific literature, including human and animal studies. It notes that “[t]he type of talc that is currently used for cosmetic purposes in the USA does not contain detectable levels of amphibole, including asbestos.”³⁷¹ J&J was aware of the IARC monographs and possessed similar volumes in its files.³⁷² Consistent with J&J’s posture towards NTP, Dr. Mann testified that J&J’s interest in participating in IARC’s review was not to interfere with it, but rather follow the process and share knowledge.³⁷³ Dr. Casalvieri’s testimony corroborates Dr. Mann’s testimony, as she described J&J “trying to get the – the complete body of

³⁶⁸ 2004.06.04 – JNJ 000003274 at 276.

³⁶⁹ Casalvieri 2022.02.15 Deposition, p. 139.

³⁷⁰ 2010 – DX9566 at 287.

³⁷¹ 2010 – DX9566 at 416 and 422.

³⁷² See, e.g., 2012 – JNJ 000451296.

³⁷³ Mann 2021.04.28 Deposition, pp. 379-381 (“Q. ... why was Johnson & Johnson having anything to do with the IARC review anyway? A. Well, we were aware that they were going to be reviewing talc and -- cosmetic talc, and so we’ve -- the IARC has the availability to make public comment, they have advisers that they accept on to -- into their meetings to -- so they have, you know, both public and industry can have a transparent process that they are working with. So this room was a place for people to come to read, to, you know, follow what’s going on. There is nothing nefarious about it. We are just trying to pay attention to what the agencies are doing and be responsive if there is something that we -- data search or something like that that might come up, but it’s basically following their process so we don’t interfere with it, we’d have no nefarious purposes. We were just trying to know what’s going on. ... Q. So what was the purpose of this war room, Dr. Mann? A. Well, consistent with my understanding, it is a place for observers whenever to come to review literature, to basically relax and, you know, have a place to go to that’s still, you know, close by. So it’s really just -- it’s a place for them to sit, to research, to have availability to the literature. It was important to us because in the past sometimes, I know for the NTP, in particular, they didn’t have all of the literature that we were aware of, so we went to some great lengths to make sure we got all of those scientific papers together and -- and shared them. It’s a -- you know, a transparency issue.”).

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evidence in front of IARC for review, understanding that they were going to do an independent assessment.”³⁷⁴

(2) Health Canada

174. In December 2018, Health Canada released a “Draft Screening Assessment” of talc that considered inhalation and perineal exposure to talc not contaminated with asbestos or other impurities, and concluded that “talc... may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.”³⁷⁵ The draft screening assessment stated that talc posed “no critical health effects via oral or dermal routes of exposure,” “non-cancer lung effects” from inhalation exposure, but that meta-analyses of available human studies “indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer.”³⁷⁶

175. As part of its process, Health Canada allowed for a public comment period of 60 days following the publication of its draft screening assessment of talc.³⁷⁷ As a general matter, Health Canada invites general comments that may relate to the transparency of Health Canada’s assessment and whether there is additional information that was not included in the assessment that could impact the conclusion.³⁷⁸ Technical comments are also invited, and may relate to issues such as appropriately identifying vulnerable populations, including key sources of exposure and hazard studies, identifying critical uncertainties,

³⁷⁴ Casalvieri 2022.02.15 Deposition, pp. 257-258 (“Q. And what specific work did J&J Consumer do in connection with the IARC process? ... THE WITNESS: I -- the -- I -- the IARC process is -- what’s the word? It’s the more closed process. It’s not like CPC or when they put out a -- a CIR review where they -- they ask for a call for information. IARC did not call for information. They did not allow members from industry to participate. And that’s their process. That’s okay. We -- that’s what we have to deal with. So there was discussion about, again, just trying to get the -- the complete body of evidence in front of IARC for review, understanding that they were going to do an independent assessment. We weren’t trying to influence that. We just wanted to make sure that they were looking at the fair body of evidence.”).

³⁷⁵ “Draft Screening Assessment Talc,” *Health Canada*, December 2018, available at <https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/draft-screening-assessment-talc-mg3h2sio34.html>, pp. iii, 1, 29.

³⁷⁶ “Draft Screening Assessment Talc,” *Health Canada*, December 2018, p. iii. The draft screening assessment went on to say that with respect to a positive association between talc and ovarian cancer, the “available data are indicative of a causal effect.”

³⁷⁷ “Public comment process on risk assessment documents,” *Health Canada*, February 11, 2022, available at <https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/public-comment-process-risk-assessment-documents.html> (“During the 60-day public comment period, any person may self-identify as a stakeholder wishing to be further consulted and engaged and submit any kind of information that is relevant to the substances included and assessed in the risk assessments.”).

³⁷⁸ “Public comment process on risk assessment documents,” *Health Canada*, February 11, 2022, available at <https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/public-comment-process-risk-assessment-documents.htm>.

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and commenting on the appropriateness of the risk characterization and possible risk management.³⁷⁹

176. Consistent with J&J's prior actions, J&J and other industry participants in the Cosmetics Alliance Canada submitted scientific responses during that comment period,³⁸⁰ and Health Canada granted J&J and others an April 24, 2019 meeting.³⁸¹ J&J noted that as of the release of Health Canada's draft screening assessment, "no global regulatory authority has concluded there is a link between talc and cancer. This is because the weight of the evidence does not support this conclusion, and the meta-analysis cited by Health Canada does not consider all scientific evidence and cohort studies with equal weight."³⁸² J&J expressed that it would "continue to advocate for evidence-based, independent analysis of cosmetic talc" and sought to "[e]ducate government and stakeholders on the science of cosmetic talc's safety."³⁸³ Internally, J&J discussed various scenarios depending on the results of the final report from Health Canada, including that confirmation of risk by Health Canada could result in adding warning labels to J&J baby powder with continued sales or removing the product from the market.³⁸⁴ This engagement with Health Canada, and discussion of how to proceed if the

³⁷⁹ "Public comment process on risk assessment documents," *Health Canada*, February 11, 2022, available at <https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/public-comment-process-risk-assessment-documents.htm>.

³⁸⁰ See 2019.02.06 – JNJTALC001195924 at 924 ("In accordance with subsection 77(5) of the *Canadian Environmental Protection Act, 1999*, (CEPA, 1999) Johnson & Johnson Inc. is providing comments to the Government of Canada on the above consultation. We understand that the Screening Assessment Report and the accompanying Risk Management Scoping document are both draft reports and the proposed conclusions are subject to change upon review of written comments and scientific considerations submitted by stakeholders. To assist your review of talc safety, we are providing a copy of the Johnson & Johnson Inc. submission provided to the United States Food and Drug Administration (FDA) on March 17, 2016. This submission includes a summary of publications on talc safety and ovarian cancer, relevant post-marketing talc safety data, and information on chemistry, manufacturing, and controls. In addition, we are also including an addendum which summarizes the epidemiologic literature published since the creation of the report for the FDA (March 2016 to January 30, 2019)."); Undated – JNJTALC001193792 at slide 2 ("Comment Period (Submitted Feb 6) Cosmetics Alliance Canada, IMA-NA and others submitted scientific response [...] J&J submitted complementary letter and materials provided to FDA to support position.").

³⁸¹ 2019.04.01 – JNJTALC001192601 at 602 (Email from Beta Montemayor of Cosmetic Alliance Canada: "Further, to previous communiques, Health Canada has agreed to meeting on the **afternoon of Wednesday, April 24, 2019, in Ottawa.**").

³⁸² Undated – JNJTALC001193792 at slide 2 ("Comment Period (Submitted Feb 6) Cosmetics Alliance Canada, IMA-NA and others submitted scientific response [...] J&J submitted complementary letter and materials provided to FDA to support position.").

³⁸³ Undated – JNJTALC001193792 at slide 3 and slide 7.

³⁸⁴ Undated – JNJTALC001193792 at slide 6. I note that in April 2021, Health Canada released its final "Screening Assessment" of talc, which maintained the conclusion from Health Canada's December 2018 "Draft Screening Assessment." See "Screening Assessment Talc," *Health Canada*, April 2021, available at

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regulatory guidance is inconsistent with the company's view of the science, is another example of J&J engaging in sensemaking, just as I would expect to see in an organization actively involved in evaluating and updating, if needed, its "map" of understanding.

(3) IWGACP

177. J&J's engagement with regulators has continued in recent years. In 2018, the FDA and the University of Maryland hosted a Joint Institute for Food Safety and Applied Nutrition "Asbestos in Talc Symposium."³⁸⁵ "The purpose of the symposium was to provide a forum for experts in asbestos mineral analysis, academicians and regulators to share knowledge on testing approaches aimed at adequately analyzing talc-containing products for the presence of asbestos fibers."³⁸⁶ The FDA requested that J&J provide a list of recommended talc testing experts for its workshop, which the company did.³⁸⁷ Following that symposium, the FDA formed the Interagency Working Group on Asbestos in Consumer Products ("IWGACP") with representatives from eight federal agencies "to support the development of standardized test methods for asbestos and other mineral particles of health concern in talc."³⁸⁸

178. In February 2020, the FDA held a public hearing to announce and discuss the preliminary recommendations from the IWGACP.³⁸⁹ It also recognized the benefits to multiple layers of testing by multiple methods, including PLM and TEM – both tests J&J has routinely performed since the 1970s.³⁹⁰ Finally, the FDA proposed the counting and reporting of all

<https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/screening-assessment-talc.html>, pp. iii, 45-46. As I discuss later in **Section IV.C.4.c**, J&J already decided to permanently discontinue talc-based J&J baby powder almost one year prior (May 2020) in conjunction with a portfolio assessment that resulted in the discontinuation of about 100 SKUs. J&J shared its plans with Health Canada in a letter dated the same day as its press release. *See* 2020.05.19 – JNJTALC001436540 at 540; "Johnson & Johnson Consumer Health Announces Discontinuation of Talc-based Johnson's Baby Powder in U.S. and Canada," *Johnson & Johnson*, available at <https://www.jnj.com/our-company/johnson-johnson-consumer-health-announces-discontinuation-of-talc-based-johnsons-baby-powder-in-u-s-and-canada>.

³⁸⁵ *See* "2018 Asbestos in Talc Symposium," *JIFSAN*, available at <https://jifsan.umd.edu/events/2018-asbestos-in-talc-symposium>.

³⁸⁶ "2018 Asbestos in Talc Symposium," *JIFSAN*, available at <https://jifsan.umd.edu/events/2018-asbestos-in-talc-symposium>.

³⁸⁷ *See* 2018.06.20 – JNJTALC000882015.

³⁸⁸ *See* IWGACP, "Preliminary Recommendations on Testing Methods for Asbestos in Talc and Consumer Products Containing Talc," *FDA*, January 6, 2020, available at <https://www.fda.gov/media/134005/download>.

³⁸⁹ *See* "FDA Issues Update Regarding Information Presented at Talc Public Meeting," *FDA*, August 18, 2020, available at <https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-update-regarding-information-presented-talc-public-meeting>.

³⁹⁰ *See* **Figure 3**.

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elongated mineral particles regardless of whether they are asbestiform or not.³⁹¹ J&J submitted comments in response to the FDA's "Preliminary Recommendations on Testing Methods for Asbestos in Talc and Consumer Products Containing Talc," noting that there is scientific data indicating that asbestiform and non-asbestiform minerals lead to different pathological outcomes and urging the FDA to withdraw the recommendations and pursue evidence-based decision making.³⁹² On August 18, 2020, the FDA "issued an update intended to provide additional clarity" regarding information posted on its website and discussed at the February 2020 public meeting.³⁹³ The FDA emphasized that the IWGACP Executive Summary and related presentations "were meant solely to solicit scientific feedback on the issues raised and should not be used for any other purpose."³⁹⁴ The update further clarified that "[t]he FDA and members of the IWGACP continue to evaluate the scientific literature and public feedback to the docket and do not have any recommendations at this time."³⁹⁵ The FDA confirmed that it would "issue draft guidance for public comment" and "propose any related regulations through a public notice and comment process" should the FDA decide to "develop recommendations with respect to standards or testing methods for asbestos in talc."³⁹⁶

179. In December 2021, the IWGACP published a white paper providing "scientific opinions of subject matter experts (SMEs) from an interagency working group related to testing cosmetic products containing talc and talc intended for use in cosmetics for the presence of asbestos, as well as other potentially harmful amphibole particles that can affect cosmetic product safety."³⁹⁷ The white paper acknowledges "long-recognized shortcomings in specificity and sensitivity to detect the presence of asbestos and similar

³⁹¹ See IWGACP, "Preliminary Recommendations on Testing Methods for Asbestos in Talc and Consumer Products Containing Talc," *FDA*, January 6, 2020, available at <https://www.fda.gov/media/134005/download>.

³⁹² See "Re: Docket No. FDA-2020-N-0025: Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc: Public Meeting: Request for Comments," *FDA*, March 4, 2020.

³⁹³ See "FDA Issues Update Regarding Information Presented at Talc Public Meeting," *FDA*, August 18, 2020, available at <https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-update-regarding-information-presented-talc-public-meeting>.

³⁹⁴ See "FDA Issues Update Regarding Information Presented at Talc Public Meeting," *FDA*, August 18, 2020, available at <https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-update-regarding-information-presented-talc-public-meeting>.

³⁹⁵ See "FDA Issues Update Regarding Information Presented at Talc Public Meeting," *FDA*, August 18, 2020, available at <https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-update-regarding-information-presented-talc-public-meeting>.

³⁹⁶ See "FDA Issues Update Regarding Information Presented at Talc Public Meeting," *FDA*, August 18, 2020, available at <https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-update-regarding-information-presented-talc-public-meeting>.

³⁹⁷ See IWGACP, "White Paper: IWGACP Scientific Opinions on Testing Methods for Asbestos in Cosmetic Products Containing Talc," *FDA*, December 2021, available at https://downloads.regulations.gov/FDA-2020-N-0025-0053/attachment_1.pdf, p. 4.

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mineral particles” with J4-1, and recommends using “both PLM and TEM methods to identify/report, at minimum, the presence of asbestos, other amphibole minerals, and talc particles exhibiting non-platy morphology.”³⁹⁸ This recommendation is consistent with J&J’s “map” of the relevant scientific knowledge, as J&J adopted the industry-standard J4-1 method³⁹⁹ but also exceeded the industry standard by requiring routine TEM testing as early as the 1970s.⁴⁰⁰ Decades later, the testing methods used by J&J remain consistent with those used by regulators currently.⁴⁰¹

**c. Johnson & Johnson’s Incentives, Motivations, and Actions
Regarding the Recent Baby Powder Recall**

180. Against this backdrop of collaboration with the FDA, on October 16, 2019, the FDA notified J&J that a sample of baby powder, Lot #22318RB, tested positive for sub-trace levels of chrysotile at the FDA’s contract lab, AMA Analytical Services, Inc. (“AMA”).⁴⁰² Less than two days after hearing of this positive testing, “out of an abundance of caution,” J&J voluntarily recalled the affected lot⁴⁰³ and instructed regional regulatory affairs leaders to assess their obligations to notify local health authorities even though the recalled batch may not have been distributed to all regions.⁴⁰⁴ J&J simultaneously convened its Quality Review Board and opened an investigation into

³⁹⁸ See IWGACP, “White Paper: IWGACP Scientific Opinions on Testing Methods for Asbestos in Cosmetic Products Containing Talc,” *FDA*, December 2021, available at https://downloads.regulations.gov/FDA-2020-N-0025-0053/attachment_1.pdf, pp. 4-5.

³⁹⁹ See 1977.08.12 – DX7144 at 2 (Windsor 66 Specification).

⁴⁰⁰ See 1978.02.23 – DX7147 at 1 (“[W]e need to recognize that Windsor Minerals and Johnson and Johnson have exercised more extensive controls and testing in the past than just meeting the J4-1 requirement. Furthermore, we intend continuing to surpass the industry testing as reflected by CTFA’s J4-1.”); see also 1977.04.29 – DX7141 (TM7024 Specification). J&J also routinely tested for serpentine minerals using differential thermal analysis. See 1977.06.28 – DX7143; 1977.04.05 – JNJ 000021787.

⁴⁰¹ Consistent with IWGACP’s recommendation, the FDA has conducted recent tests of talc-containing cosmetic products using PLM and TEM. See, e.g., “FDA Summary of Results from Testing of Official Samples of Talc-Containing Cosmetics for Asbestiform Fibers Completed by AMA Laboratories in 2023,” *FDA*, April 5, 2024, available at <https://www.fda.gov/cosmetics/cosmetic-ingredients/fda-summary-results-testing-official-samples-talc-containing-cosmetics-asbestiform-fibers-completed>.

⁴⁰² See 2019 – JNJTALC001282315 at 315.

⁴⁰³ 2019.10.18 – JNJTALC001282177 at 1. See also “Baby powder manufacturer voluntarily recalls products for asbestos,” *FDA*, October 18, 2019, available at <https://www.fda.gov/news-events/press-announcements/baby-powder-manufacturer-voluntarily-recalls-products-asbestos>. The FDA did not believe this issue constituted a Class 1 recall (“a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences of death”); instead, the recall was classified as Class II (“a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote”). See 2019.12.06 – DX8358; 2019.11.27 – DX8355; 2019.11.19 – DX8356; 2019.11.19 – DX8357.

⁴⁰⁴ See 2019.10.18 – JNJTALC001300939.

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potential contamination.⁴⁰⁵ Additionally, J&J's Office of Consumer Medical Safety conducted a Health Hazard Evaluation of the risk to consumers should J&J confirm the FDA's results.⁴⁰⁶ Throughout the investigation, J&J updated the FDA on its findings, including the numerous concerns J&J found in AMA's report.⁴⁰⁷

181. In addition to identifying these issues, J&J contracted independent laboratories RJ Lee and Bureau Veritas to test samples from the FDA's bottle, the affected lot, and lots manufactured before and after the affected lot by a combination of four different test methods. Neither lab found chrysotile or any other asbestiform minerals in 155 tests conducted.⁴⁰⁸
182. Summarizing this testing, J&J issued its Investigation Summary in early December 2019, reporting the results of the 155 tests conducted by the two laboratories.⁴⁰⁹ J&J made the Investigation Summary and underlying testing data publicly available online.⁴¹⁰ In the final investigation report, J&J also disclosed that it conducted site visits and requested members of the supply chain to conduct internal investigations as part of a root cause analysis.⁴¹¹
183. However, given the enormous impact of COVID-19 on health care generally and on J&J specifically, J&J's Consumer Health division conducted a portfolio assessment that

⁴⁰⁵ See 2019.10.17 – JNJALC001282306. See also 2019 – JNJALC001282315 at 315. J&J's internal communications note that the Quality Review Board recalled the product out of an abundance of caution while its investigation continued, and J&J advised its regional leaders to proactively notify local health authorities even if the batch in question was not distributed to that region. See 2019.10.17 – JNJALC001300890 and 2019.10.18 – JNJALC001300939.

⁴⁰⁶ See 2019.10.18 – JNJALC001282155. J&J updated this Health Hazard Evaluation in December 2019 to include the investigation results. The Addendum to the Health Hazard Evaluation noted that the "resulting investigation has determined that JBP does not contain chrysotile based on the totality of evidence." See 2019.12.17 – JNJALC001296322.

⁴⁰⁷ See 2019 – JNJALC001282315. See also 2019.11.04 – JNJALC001282309. The J&J review of AMA's tests raised concerns including: unclear chain-of-custody; improper storage conditions, testing protocol, and methodology; and potential contamination from other tests that may have biased AMA's results.

⁴⁰⁸ See 2019.12.03 – DX8912 at 1 ("Two different third-party labs, RJ Lee and [Bureau] Veritas Labs, conducted 155 tests using 4 different methods. No chrysotile was found in any of these 155 tests."). RJ Lee's initial testing of one finished good sample and two raw material samples found the presence of chrysotile; however, after investigation, "these results were invalidated due to laboratory contamination from a portable air conditioner used in an auxiliary room at RJ Lee." RJ Lee's final report "indicated that no asbestos was detected in any of the samples tested." See 2019.12.03 – DX8912 at 2-3; 2019.10.28 – DX8914 at 1. This extensive testing led J&J to conclude that "we are now more than 99% confident that the chrysotile found in that [sic] AMA's results is a product of lab contamination and not something found in our product." See 2019.11.04 – JNJALC001282309.

⁴⁰⁹ See 2019.12.03 – DX8912.

⁴¹⁰ See "Test Results," *Johnson & Johnson*, available at <https://jjcloud.ent.box.com/s/3g7nbp268fu3vbjjdovxvyrqzz7wvuw4w>.

⁴¹¹ See Undated – JNJALC001284148 at 161-164.

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resulted in a decision to discontinue approximately 100 SKUs.⁴¹² This included talc-based Johnson's Baby Powder in the United States and Canada. Declining sales of the product in the United States and Canada were also attributed to changes in consumer habits resulting from misinformation around the safety of the product driven by litigation advertising.⁴¹³ The decision to discontinue the product in 2020 was accompanied by a statement that "Johnson & Johnson remains steadfastly confident in the safety of talc-based Johnson's Baby Powder. Decades of scientific studies by medical experts around the world support the safety of [the] product."⁴¹⁴ There is no basis to conclude or suggest that J&J discontinuing talc-based Johnson's Baby Powder in the United States and Canada is evidence that the product contained asbestos or is otherwise unsafe.⁴¹⁵ On the contrary, J&J's efforts to "prioritize high-demand products" in order to facilitate "social distancing in manufacturing and distribution facilities" demonstrates that J&J is prioritizing the wellbeing of consumers and its employees in the context of a changing health care landscape.⁴¹⁶

184. In 2022, J&J's Consumer Health division further announced that it would discontinue sales of talc-based Johnson's Baby Powder globally in 2023 and transition to all cornstarch-based powder products as part of its worldwide portfolio assessment.⁴¹⁷ J&J's announcement emphasized that this was a "commercial decision" and that its "position on

⁴¹² See 2020.05.14 – JNJTALC001435679 at 382.

⁴¹³ See 2020.05.11 – JNJTALC001448376 at 377, 379-380.

⁴¹⁴ See "Johnson & Johnson Consumer Health Announces Discontinuation of Talc-based Johnson's Baby Powder in U.S. and Canada," *Johnson & Johnson*, available at <https://www.jnj.com/our-company/johnson-johnson-consumer-health-announces-discontinuation-of-talc-based-johnsons-baby-powder-in-u-s-and-canada>; Testimony from Johnson & Johnson Consumer, Inc. Vice President of Finance, Christopher Picariello, supports the claim of decreased demand for talc-based Johnson's Baby Powder in recent years. See Deposition of Christopher Picariello, January 11, 2019, 97:3 - 98:10 ("Q. So, Mr. Picariello, what you did -- for purposes of this declaration is you calculated sales of --- the allocation of sales between Johnson's Baby Powder talc and cornstarch since 2009; is that right? A. That's correct... Q. Okay. And so for all but 2017, cornstarch -- baby powder containing cornstarch was more -- you sold more of those than -- you had more revenues from those than baby powder containing talc; is that correct? A. That's correct.").

⁴¹⁵ See Deposition of Susan Nicholson, December 9, 2020, p. 457 ("A. And let me be clear. This was a business decision and this was a discontinuation of a sku, so part of that process does not include recall of a product. If there were a safety issue, yes, we could recall and we certainly have the authority, but there was not -- there was not a safety issue in this case, so it is two completely different lines of activity.").

⁴¹⁶ See "Johnson & Johnson Consumer Health Announces Discontinuation of Talc-based Johnson's Baby Powder in U.S. and Canada," *Johnson & Johnson*, available at <https://www.jnj.com/our-company/johnson-johnson-consumer-health-announces-discontinuation-of-talc-based-johnsons-baby-powder-in-u-s-and-canada>.

⁴¹⁷ See "Johnson & Johnson Consumer Health to Transition Global Baby Powder Portfolio to Cornstarch," *Johnson & Johnson*, available at <https://www.jnj.com/media-center/press-releases/johnson-johnson-consumer-health-to-transition-global-baby-powder-portfolio-to-cornstarch>.

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the safety of [its] cosmetic talc remains unchanged.”⁴¹⁸ J&J goes on to state: “We stand firmly behind the decades of independent scientific analysis by medical experts around the world that confirms talc-based JOHNSON’S® Baby Powder is safe, does not contain asbestos, and does not cause cancer.”⁴¹⁹ Similar to J&J’s earlier decision to discontinue talc-based Johnson’s Baby Powder in the U.S. and Canada, there is no basis to conclude or suggest that J&J discontinuing talc-based Johnson’s Baby Powder globally is evidence that the product contained asbestos or is otherwise unsafe.

185. The continued interactions with regulators and the recent recalls demonstrate that J&J continues to engage its sensemaking capabilities. The FDA’s claimed identification of asbestos in Johnson’s Baby Powder was another disruptive ambiguity to J&J’s “map” of existing scientific knowledge. J&J did not just rely on its current “map” to simply state that the FDA was wrong; instead, J&J made use of its robust sensemaking capabilities established during the development and adaptation of its “map” and devoted attention and significant resources to achieve a comprehensive understanding of the FDA’s finding. J&J’s commitment to developing this understanding through active sensemaking is thus consistent with its past actions and behaviors. The voluntary recall and subsequent investigation demonstrate that J&J’s active engagement in sensemaking is part of its larger commitment to scientific knowledge that serves the wellbeing of consumers. These actions are not evidence that the product contained asbestos or was otherwise unsafe, as the litigation in this matter suggests. The same is true for J&J’s decision to discontinue talc-based Baby Powder globally. There is no evidence that this decision was motivated by concerns with the safety of the product. Instead, this assumption is part of plaintiffs’ flawed causal narrative.

d. External Evaluation of Johnson & Johnson’s Incentives, Motivations, and Actions Regarding the Safety of Its Baby Powder

186. In 2018 and 2019, J&J’s Board of Directors received a series of letters (“Demand Letters”) from shareholders that urged J&J to “investigate and pursue litigation against certain current and former J&J officers and directors relating to the Company’s sales of certain talc-based products, including Baby Powder and Shower to Shower..., which the

⁴¹⁸ See “Johnson & Johnson Consumer Health to Transition Global Baby Powder Portfolio to Cornstarch,” *Johnson & Johnson*, available at <https://www.jnj.com/media-center/press-releases/johnson-johnson-consumer-health-to-transition-global-baby-powder-portfolio-to-cornstarch>.

⁴¹⁹ See “Johnson & Johnson Consumer Health to Transition Global Baby Powder Portfolio to Cornstarch,” *Johnson & Johnson*, available at <https://www.jnj.com/media-center/press-releases/johnson-johnson-consumer-health-to-transition-global-baby-powder-portfolio-to-cornstarch>.

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Demand Letters allege are unsafe, contain asbestos, and cause cancer.”⁴²⁰ In response, J&J’s Board retained Gibson, Dunn & Crutcher LLP to independently investigate and analyze the facts underlying the Demand Letters, which resulted in the Special Investigation Report that was provided to the Board on July 10, 2020.⁴²¹ After 20 months of interviewing witnesses and reviewing documents produced in related talc litigation, deposition and trial transcripts, scientific studies and testing documents, and other relevant materials, the independent investigation concluded that J&J “has (and has long had) comprehensive and well-functioning sets of internal controls and reporting processes related to product safety, product quality, and public disclosures.”⁴²² In fact, the independent investigation found that “Board and Company officers undertook good-faith efforts to be informed about key issues relevant to the Company’s products, including the safety of Talcum Powder Products” and that the “evidence reflects that the Company is completely committed to the safety and quality of its products; that the Talcum Powder Products are safe, are not contaminated with asbestos, and do not cause cancer; and that the Company does, in fact, have ‘substantial defenses’ to product liability lawsuits, including the Talc Litigation in particular.”⁴²³

187. Not only are the findings of the Special Investigation Report consistent with J&J’s organizational commitment to the wellbeing of consumers, but it is also significant that the findings of the investigation are consistent with the opinions in this report. Similar to the research I conducted and documentary evidence I reviewed, Gibson, Dunn & Crutcher LLP states “[t]he Company’s belief and confidence in the safety of its Talcum Powder Products is appropriately based on, among other things, the robustness of J&J’s Medical Safety and Quality & Compliance controls and reporting procedures; the high level of competence and integrity of the Medical Safety and Quality & Compliance teams and their commitment to product safety; the history of extensive testing by J&J and third-party experts that have confirmed that J&J’s Talcum Powder Products are not contaminated with asbestos; J&J’s ongoing monitoring of the relevant scientific literature and medical studies concerning the Talcum Powder Products and talc generally; and the Company’s own product safety surveillance and regular product safety reviews.”⁴²⁴

⁴²⁰ See Exhibit 6 to Verified Consolidated Stockholder Derivative Complaint, *In re: Johnson & Johnson Talc Stockholder Derivative Litigation*, “Special Investigation Report to the Board of Directors of Johnson & Johnson,” Gibson, Dunn & Crutcher LLP, July 10, 2020 (hereafter “Board Report”), p. 8.

⁴²¹ See Board Report, pp. 1, 8.

⁴²² See Board Report, pp. 9-10.

⁴²³ See Board Report, pp. 10-11.

⁴²⁴ See Board Report, pp. 12-13.

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e. Conclusion

188. The evidence described above demonstrates that J&J was actively applying and updating its “map” regarding the potential for asbestos in cosmetic talc and talc safety, consistent with what I would expect to see in an organization that prioritizes the safety of its products. J&J continued to attend to signals about the safety of baby powder, even after much of the disruptive ambiguity from the early 1970s had been resolved and its new “map” had been codified. The organization applied its “map” and its sensemaking capabilities to quickly investigate and respond to new allegations and ambiguities that arose, and regularly updated its “map” based on a continuing engagement with regulators and the scientific community.

V. CONCLUSION

189. The actions J&J took to develop scientific knowledge and affirm its perspective regarding the safety of its baby powder are described throughout my report. Over the course of decades, J&J paid attention to knowledge in the external environment; it devoted attention and resources to the interpretation of that knowledge; and it took actions as a result of any new knowledge. This is behavior I would expect to see in an organization committed to the wellbeing of consumers. J&J has demonstrated an ongoing concern about the quality and safety of its baby powder, and proactively engaged in sensemaking with regards to the possibility it was not safe.

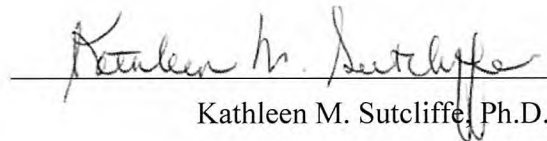
190. Since the disruptive ambiguity of the early 1970s, J&J has devoted significant resources and attention to developing, validating, disseminating, and challenging a “map” that codifies the existing scientific knowledge regarding the detection of asbestos in talc and the safety of talc. This “map” informs its internal testing, its interaction with regulators and the industry, and its research agenda. J&J’s interactions with external stakeholders have validated the accuracy of the “map” that J&J has drawn and applied. J&J and others have investigated cues from the external environment to determine whether to disconfirm other aspects of J&J’s “map” as well. Engagement with independent testing, regulatory decision making, and new scientific research has also continued to validate J&J’s “map.” In other words, J&J’s actions and decisions demonstrate a continued commitment to discussion, validation, and dissemination of scientific knowledge among researchers and external stakeholders. This commitment is realized through its sensemaking efforts, codified in the “map,” and undertaken in service to J&J’s commitment to product safety and the wellbeing of consumers. Attempts to characterize J&J’s incentives, motivations, or actions otherwise are unsupported by the record and contradicted by a properly conducted assessment, as I have conducted and documented in this report.

191. To adequately support their conclusions about J&J as an organization, plaintiffs would need to conduct an organizational assessment of their own that leverages an established

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conceptual framework and research methodology based in organizational theory. Instead, they engage in cherry-picking, a biased review of the evidence, and inappropriate extrapolation to make broad generalizations about J&J. For these reasons, it is my opinion, based on decades of experience in the field of organizational science, that plaintiffs' conclusions about J&J as an organization are flawed.

192. The results of my assessment, based on decades of documentary evidence, are unambiguous: In my opinion, and in contrast to plaintiffs' flawed conclusions, the evidence I reviewed demonstrates J&J's commitment to the safety and purity of its baby powder products. Over many decades, J&J relied on scientific knowledge and data, including a rigorous testing program, to verify the safety of its baby powder products, and was transparent with those outside the organization regarding the same. J&J actively investigated and responded to concerns about the safety of its baby powder products, and engaged with industry and regulatory stakeholders as well. J&J's actions were consistent with its organizational priorities, as they have been articulated consistently over many decades,⁴²⁵ as well as with behavior I would expect to see in an organization committed to the wellbeing of consumers.



Kathleen M. Sutcliffe, Ph.D.

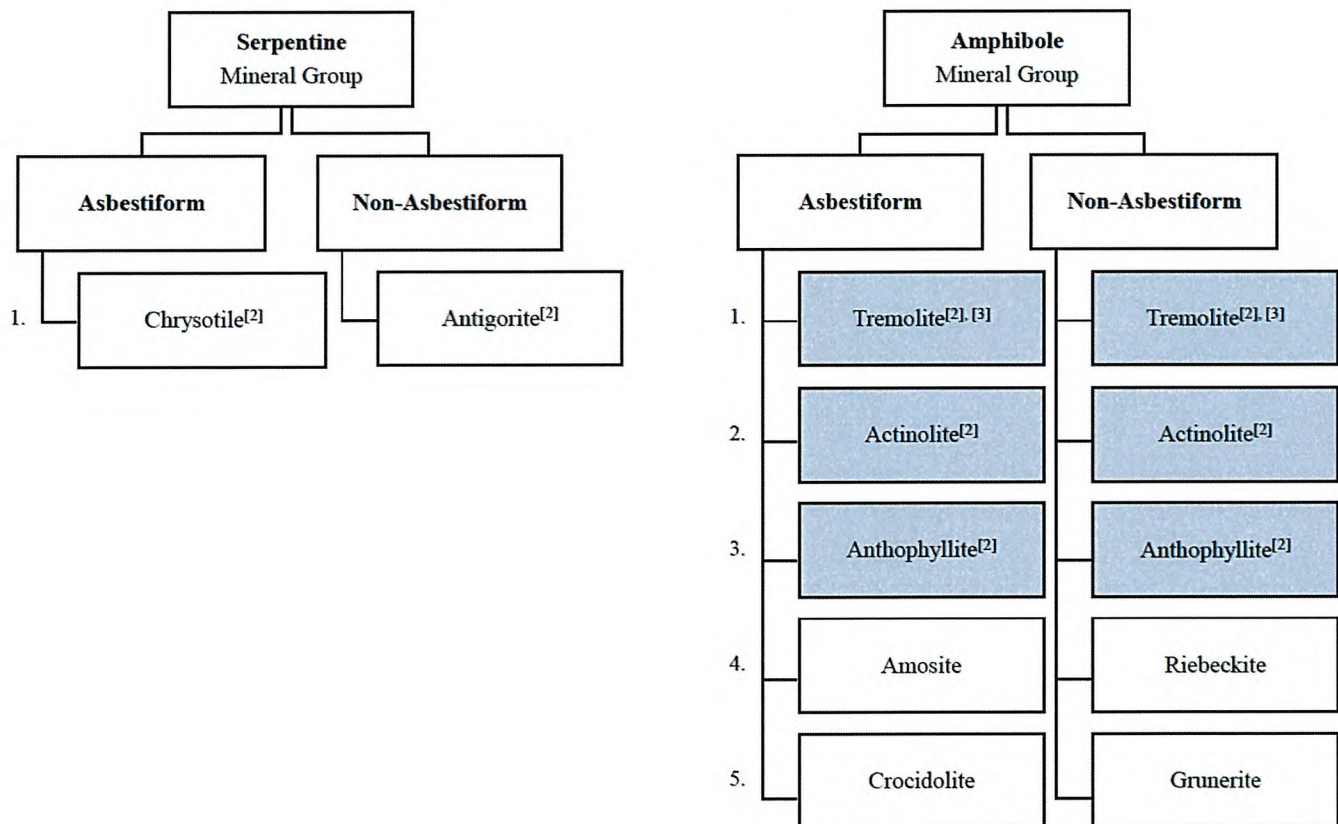
April 12, 2024

⁴²⁵ See, e.g., testimony from J&J's chief medical officer, Dr. Edwin Kuffner: "If I thought [baby powder] needed a cancer warning, that product would've been off the market." Bolado, Carolina, "J&J's CMO Says He Would've Pulled Talc If It Caused Cancer," *Law360*, February 27, 2024, available at <https://www.law360.com/articles/1807513/j-j-s-cmo-says-he-would-ve-pulled-talc-if-it-caused-cancer>.

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Figure 1
Classification of Asbestiform and Non-Asbestiform Minerals^[1]

Each Mineral has an Asbestiform and Non-Asbestiform Name. Minerals with the Same Name are Highlighted in Blue.^[2]



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Figure 1
Classification of Asbestiform and Non-Asbestiform Minerals^[1]

Notes:

[1] Asbestos and asbestiform are “two commonly used terms that lack mineralogical precision.” Asbestos describes “certain minerals that have crystallized in a particular macroscopic habit with certain commercially useful properties.” Asbestiform applies to “minerals with a macroscopic habit similar to that of asbestos.” Similarly, terms such as fibrous and fiber can refer to “particles that occur in an asbestiform habit but also to particles that occur in other fibrous habits or as needle-like (acicular) single crystals... Thus it is not clear, even from a single reference source, exactly what range of morphologies are described by these terms and the degree of overlap, if any.” 2011.04 - DX9315 at v, 7-9.

[2] Minerals can be found as *both* asbestiform and non-asbestiform. These minerals occur more commonly in a non-asbestiform habit. When these minerals are non-asbestiform, they can be referred to as “mineral fibers” or “cleavage fragments.” See 2011.04 - DX9315 at 7-9. Tremolite, Actinolite, and Anthophyllite (highlighted in blue) have the same name in both its asbestiform and non-asbestiform.

[3] The mineral tremolite is rarely found as asbestiform and more commonly seen as nonasbestiform. In 1972, the FDA agreed that the “massive form of tremolite should not be considered as asbestos.” 1972.08.11 - DX8371 at 2. See also **Figure 4**.

Sources:

[A] 2011.04 - DX9315 (NIOSH Current Intelligence Bulletin 62: Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research).

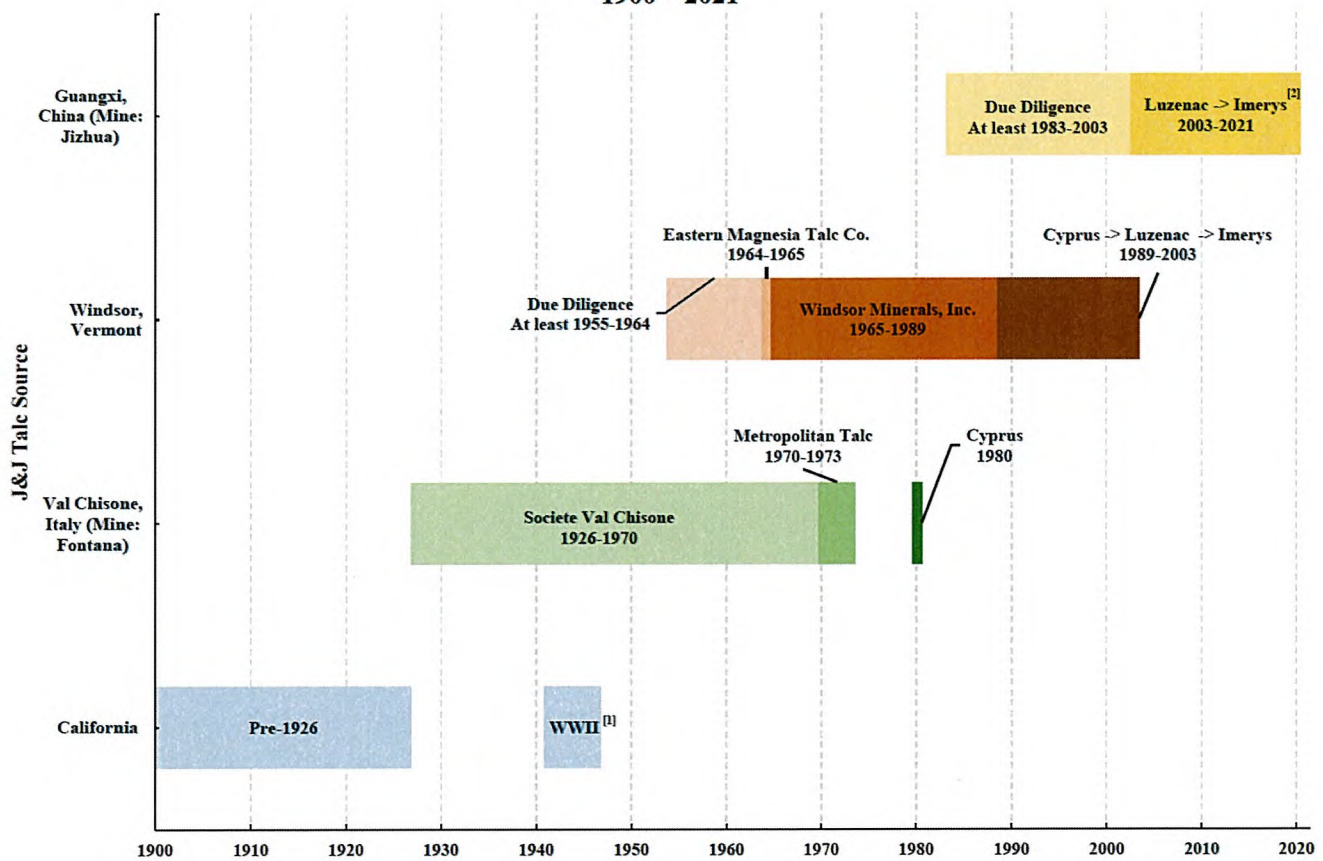
[B] “IARC Monographs on the Evaluation of Carcinogenic Risks to Humans,” *World Health Organization*, Volume 93, 2010.

[C] 1972.08.11 - DX8371.

[D] “IARC Monographs: Arsenic, Metals, Fibres, and Dusts: A Review of Human Carcinogens,” *World Health Organization*, Vol. 100C, 2012, available at <https://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Arsenic-Metals-Fibres-And-Dusts-2012>, pp. 219-309.

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Figure 2A
Cosmetic Talc Sources, Mines, and Suppliers
1900 – 2021



F-2A.i

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Figure 2A
Cosmetic Talc Sources, Mines, and Suppliers
1900 – 2021

Notes:

[1] California was used in addition to Val Chisone, Italy during World War II. Starting in January 1941, J&J used 50% Italian talc and 50% Californian talc. In June 1946, J&J returned to using 100% Italian talc.

[2] Luzenac was acquired by IMERYS in 2011. See “Imerys Makes Binding Offer and Enters Exclusive Discussions With Rio Tinto for the Acquisition of the Luzenac Talc Group,” *PRNewswire*, February 23, 2011, available at <https://www.prnewswire.com/news-releases/imerys-makes-binding-offer-and-enters-exclusive-discussions-with-rio-tinto-for-the-acquisition-of-the-luzenac-talc-group-116717179.html>.

[3] According to Dr. Hopkins, in 1972, “testing commissioned by J&J and performed by Dr. Pooley confirmed an absence of asbestos in J&J’s Italian talc mine as well as in product samples sourced from that mine dating back to 1949.” See 2020.06.04 - Hopkins Declaration and Exhibits, p. 2. See also 1972.09.28 – DX7044; 1972.09.08 – DX7038.

[4] According to Dr. Hopkins, in 2003, “J&J completed its qualification of the Jizhua talc mine in Guangxi, China following testing of ore body samples drawn over many years.” See 2020.06.04 - Hopkins Declaration and Exhibits, p. 3. See also 1984.05.08 - JNJALC000166354; 2003.09.30 - JNJ 000375304; 2003.12.04 - JNJ 000375283.

Sources:

[A] Guangxi, China: 1983.03 - JNJ 000059273; 1984.05.08 - JNJALC000166354; 1987.02 - JNJ 000865760; 1990.06.21 - JNJALC000128630; 1990.11.05 - JNJALC000128639; 1992.08.26 - JNJALC000167162; 1992.02.12 - JNJ 000867464; 1992.03.04 - JNJALC000216351; 1992.06.09 - JNJALC000166335; 1993.09.29 - JNJALC000216179; 2002.08.12 - JNJ 000564189; 2003.04.17 - JNJALC000439729; 2003.12.04 - JNJ 000375283; 2003.09.30 - JNJ 000375304.

[B] Val Chisone, Italy: Undated - JNJ 000290692; Undated - JNJ 000868288; 1970 - JNJ 000280197; 1970.07.10 - JNJ 000090066; 1972.10.17 - DX8372 at 2; 1973.12.05 - JNJ 000231336; 1980.01.14 - JNJ 000237361; 1980.01.31 - JNJ 000237357; 1980.07.21 - JNJ 000237356.

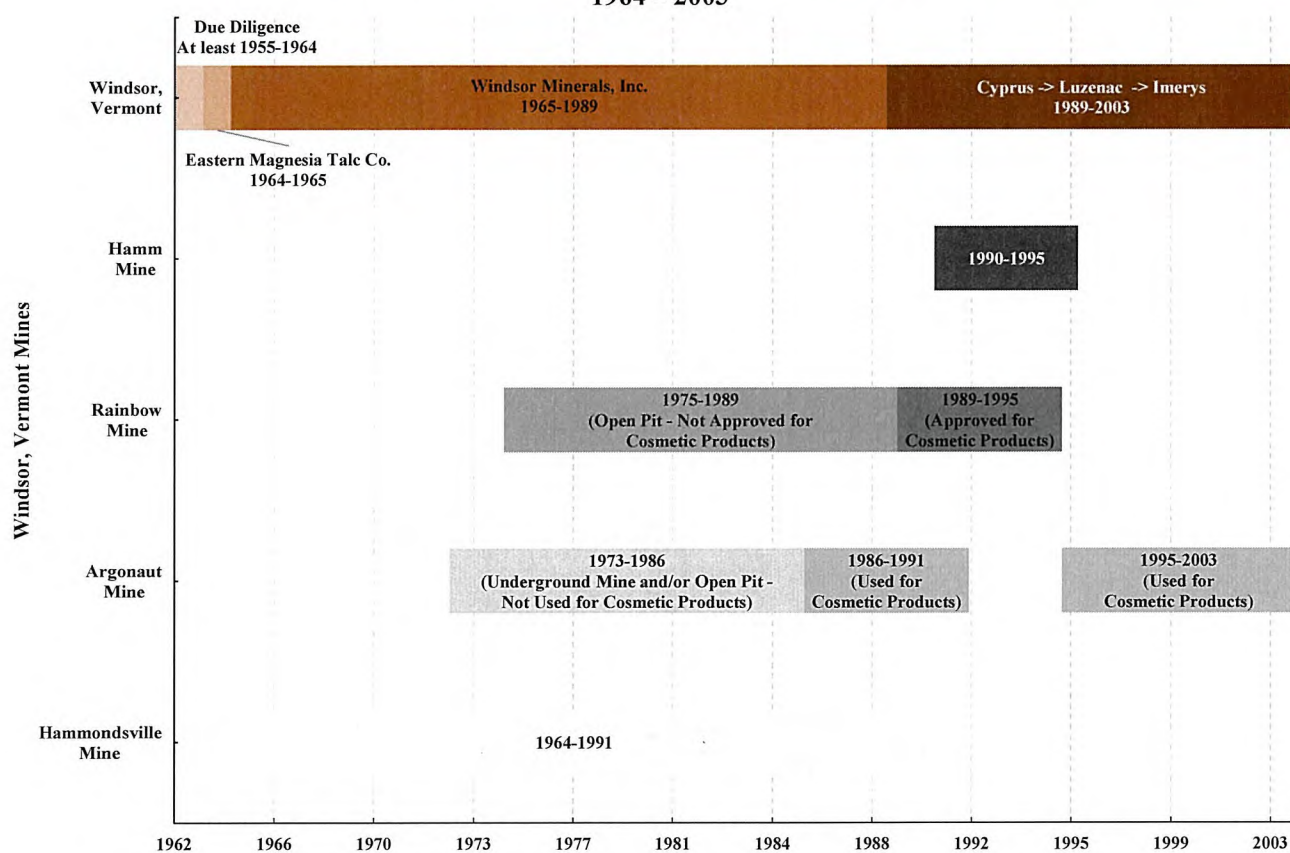
[C] Windsor, Vermont: Undated - JNJ 000868288; 1961.06.06 - JNJALC000129140; 1962 - DX7988 and 1966.07.13 - JNJALC000348143; 1964.04.21 - JNJ 000235105; 1965.05.01 - JNJ 000261596 at 597; 1965.09.22 - IMERYS 162826; 1965.10.07 - JNJ 000868191; 1963.05.27 - JNJ 000087425; 1969.04.24 - JNJ 000089431; 1970.07.10 - JNJ 000090066; 1989.05.30 - JNJALC000387698 and Undated - DX8194 at 2; 2003.12.04 - JNJ 000375283.

[D] California: 1966.07.13 - DX7731.

[E] 2020.06.04 - Hopkins Declaration and Exhibits.

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Figure 2B
Windsor, Vermont Cosmetic Talc Mines and Suppliers
1964 – 2003



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Figure 2B
Windsor, Vermont Cosmetic Talc Mines and Suppliers
1964 – 2003

Notes:

[1] According to Dr. Hopkins, in 1970, "testing commissioned by J&J and performed by the Colorado School of Mines Research Institute as part of core drilling campaign was used to understand the Hammondsville, Vermont ore body and confirmed an absence of asbestos. ... In 1972, testing commissioned by J&J and performed by Dr. Pooley confirmed an absence of asbestos in J&J's Hammondsville, Vermont talc mine. ... In 1974, McCrone completed a six-month ore study of the Hammondsville, Vermont ore body." See 2020.06.04 - Hopkins Declaration and Exhibits, 1970.09.21 - JNJ 000245000, 1970.12.04 - JNJ 000245002, 1972.10 - DX7046, 1974.08.08 - DX8621, 1974.08.10 - DX8814, 1974.12.31 - DX7099, and 1978.11.14 - DX7149.

[2] In 1991, Hammondsville was phased out and closed. See, e.g., Undated - IMERYYS 117598 at 7599.

[3] Argonaut started as an underground mine in 1973 and, in 1974, "J&J began its assessment of the Argonaut, Vermont ore body which included testing by McCrone." See 2020.06.04 - Hopkins Declaration and Exhibits and 1974.04.24 - JNJ 000222859. Argonaut was qualified in 1975, but was not qualified for use in J&J cosmetic products until 1986. See Undated - JNJ 000348019. The mine was expanded and by 1995, all mining was consolidated to Argonaut. See, e.g., Undated - DX8194.

[4] Rainbow started as an open pit in 1975, but was not qualified for use in J&J cosmetic products until 1989. In 1988, Windsor Minerals had completed a study of Rainbow, but J&J did not approve its ore body for cosmetic talc production until 1989. See 2020.06.04 - Hopkins Declaration and Exhibits, 1988.10.14 - ITA-Sabatelli-000539, and 1989.05.22 - JNJ 000223445. There is no clear evidence that the Rainbow ore body was used in cosmetic talc. See 1993.08.19 - IMERYYS 427291.

[5] According to Dr. Hopkins, in 1989, "J&J began its qualification of the Hamm, Vermont ore body and by 1992, Rio Tinto Minerals had conducted multiple assessments of the Hamm ore body." See 2020.06.04 - Hopkins Declaration and Exhibits, 1989.12.12 - JNJ 000223442, and 1992.05.21 - IMERYYS 238270.

[6] Talc from various mines was frequently mixed. For example, from 1986 to 1990, a blend of Argonaut and Hammondsville ore was used to produce Grade 66 talc, and in 1991, a blend of Argonaut and Hamm ore was used to produce Grade 66 talc. See, e.g., IMERYYS 117598.

[7] The West Windsor mill was designed to process cosmetic grade ore. See 1966.04.07 - JNJ 000087299 at 7305 ("The West Windsor plant was designed to treat Hammondsville ore primarily for the production of baby talc by flotation"); 1973.01.12 - JNJ 000261816 at 821 ("Cosmetic talc production is currently concentrated at the West Windsor mill. The mill is fed from the Hammondsville mine"); 1989.05.22 - JNJ000223445 and 1995.07.21 - JNJ 000348021 (confirming use of West Windsor mill to process Rainbow and Argonaut ore into cosmetic talc). However, there were periods where industrial talc was processed at the West Windsor mill due to insufficient production capacity at other mills. See 1973 - DX8023 at 6 ("Because the obsolete Gassetts mll [sic] cannot produce all of the roofing talc which we can sell, we were forced several years ago to set up a roofing talc operation in one corner of the West Windsor mill.").

Sources:

[A] Rainbow Mine: 1993.08.19 - IMERYYS 427291; 1989.05.22 - JNJ 000223445; Undated - IMERYYS 156170; 1995.04.12 - JNJ 000240672; 1996.02.13 - JNJ 000240635; IMERYYS 117598; 1994.03.16 - DX7371.

[B] Argonaut Mine: Undated - IMERYYS 117598; 2003.12.04 - JNJ 000375283; Undated - DX8194; Undated - JNJ 000348019; 1995.07.21 - JNJ 000348021; 1995.07.18 - JNJ 000348023; 1995.04.11 - JNJ 000240673.

[C] Hamm Mine: 1993.06.21 - JNJ TALC000071190; Undated - IMERYYS 156170; 1995.04.12 - JNJ 000240672; 1996.02.13 - JNJ 000240635; Undated - IMERYYS 117598; 1994.03.16 - DX7371; Undated - JNJ 000240691.

[D] Hammondsville Mine: 1966.07.13 - JNJ TALC000348143 at 144; 1962 - DX7988 at 1, 3, 13; 1993.06.21 - JNJ TALC000071190; Undated - IMERYYS 117598; Undated - JNJ 000868288; 1965.10.07 - JNJ 000868191.

[E] 2020.06.04 - Hopkins Declaration and Exhibits.

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Figure 3
Timeline of Routine Testing of Johnson & Johnson's U.S. Cosmetic Talc Supply

Material	Production Stage	Frequency	Years	Tester	Method(s) ^[1]	Sources
1. Ground Talc Ore ^[2]	Grinding at the Mill ^[3]	Weekly, Bi-weekly, Tri-weekly, and Monthly ^[4]	1974-1998	The McCrone Group and Bain Environmental	TEM	[A] [B] [C]
		Monthly and Per Shipment	2003-2020	IMERYS ^[5]	XRD, PLM, TEM	[A] [D]
2. Finished Talc	Post-Flotation and Flash Drying ^[6]	Weekly, Bi-weekly, and Quarterly	1972-1987, 1990-1993	Johnson & Johnson ^[7]	XRD, DTA, PLM ^[8]	[A] [E]
		Weekly, Bi-weekly, Tri-weekly, Monthly, and Quarterly	1987-1990	ES Laboratories ^[9]	XRD, DTA, PLM	[A] [F]
		Varied ^[10]	1993-2003	IMERYS ^[5]	XRD, PLM	[A] [G]
		Quarterly	1977-1996	The McCrone Group	TEM	[A] [H]
			1996-2003	Bain Environmental	TEM	[A] [H]
	Additional Testing	Monthly ^[11]	2009-2020	IMERYS ^[5]	XRD, PLM, TEM	[A] [G]
		Quarterly	2010-2020	RJ Lee Group ^[12]	XRD, PLM, TEM	[A] [I]
3. Bottled Talc	Bottling	Yearly	1975-1985, 1993-1996, 1998-1999	Johnson & Johnson Worldwide Talc Monitoring Program, The McCrone Group, and EMV Associates	XRD, DTA, PLM, TEM, SEM ^{[13], [14]}	[A] [J]

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Figure 3
Timeline of Routine Testing of Johnson & Johnson's U.S. Cosmetic Talc Supply

Notes:

- [1] Transmission electron microscopy ("TEM") scans at 5,000X and 20,000X magnification for asbestiform minerals. TEM is a precise instrument but requires an expert operator and a sophisticated microscope beyond the means of some industry participants. *See* 1990 – DX9666; 1976.03.18 – JNJ 000330509 at 510. X-ray diffraction ("XRD") method allows for a scan of the crystalline material under an x-ray beam. However, XRD is unable to differentiate between fibrous and nonfibrous materials. *See* 1976.10.07 - DX7131; 1984 – JNJ 000224493 at 167. Polarized light microscopy ("PLM") helps determine the mineralogical purity and crystallographic habit of mineral talc. It may fail to detect finely-sized particles of asbestos. *See* 1956.02.29 - DX8360; IWGACP, "Preliminary Recommendations on Testing Methods for Asbestos in Talc and Consumer Products Containing Talc," FDA, January 6, 2020, available at <https://www.fda.gov/media/134005/download>. Differential thermal analysis ("DTA") helps detect and estimate levels of chrysotile asbestos even at low concentrations. *See* 1973.11.09 - DX7078. Scanning electron microscopy ("SEM") relies on electron beam energy to view the specimen at magnifications between 20 and 25,000 times. *See* 1972 - JOJO-MA2546-01282.
- [2] "HC" is commonly associated with Hammondsville, where J&J sourced its cosmetic talc. Yet, "HC" is sometimes used to designate other forms of talc. *See, e.g.,* 1978.12.08 - DX8378 (indicating "HC" for cosmetic talc); 1976.04.26 - DX7122 (indicating "HC" for industrial talc); 1974.08.08 - DX8111 (indicating "HC" for roofing material). "HC" ore could be used in industrial products. *See* 1973.01.12 - DX8373 (indicating the West Windsor mill produced industrial talc products using Hammondsville ore that was rejected for cosmetic use during processing). In 1987, McCrone indicated that it "Windsor's product is free of asbestos ... based on over 15 years of closely examining this product." *See* 1987.05.21 – DX7216. *See also* 1976.03.12 - DX7577.
- [3] According to Dr. Hopkins, "[a]t least as of 1955, J&J's material specification for cosmetic talc required that all cosmetic talc be free of 'acicular' or needlelike particles when examined by optical microscopy. The presence of appreciable quantities of acicular particles was cause for rejection of the talc." *See* 2020.06.04 - Hopkins Declaration and Exhibits, p. 3; 1955.02.22 - DX7000.
- [4] The McCrone Group performed weekly testing from 1974-1975, bi-weekly testing from 1975-1979, tri-weekly testing from 1979-1984, and monthly testing from 1984-1996. *See* 2020.06.04 - Hopkins Declaration and Exhibits; 1978.02.23 - DX7147; 1978.11.14 - DX7149; 1978.12.08 - DX8378. Note that Windsor Minerals conducted bi-weekly tests of ground ore samples using TEM as early as August 1973. *See* 1978.02.23 - DX7147.
- [5] Luzenac America Inc., which became a wholly owned subsidiary of Rio Tinto Minerals, was acquired by IMERYS Talc in 2011. *See* "Imerys Makes Binding Offer and Enters Exclusive Discussions With Rio Tinto for the Acquisition of the Luzenac Talc Group," *PRNewswire*, February 23, 2011, available at <https://www.prnewswire.com/news-releases/imerys-makes-binding-offer-and-enters-exclusive-discussions-with-rio-tinto-for-the-acquisition-of-the-luzenac-talc-group-116717179.html> and "Rio Tinto Unit Facing Lawsuit Over Talc Cancer Claims," *S&P Global Market Intelligence*, September 5, 2016, available at <https://www.spglobal.com/marketintelligence/en/news-insights/trending/p6cdp74kew2qastruwx3q2>. Starting in 2009, "Imerys began performing additional monitoring testing using XRD, PLM and TEM on monthly composite samples of all milled powders at its Houston location." *See* Board Report, p. 232. For the purpose of this Figure, I limit the data to 2018 because Imerys filed for bankruptcy in February 2019. *See* Board Report, p. 165.

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Figure 3
Timeline of Routine Testing of Johnson & Johnson's U.S. Cosmetic Talc Supply

- [6] In 2003, J&J transitioned its talc source from Vermont to China. *See* **Figure 2A**. According to Dr. Hopkins, “[w]hen J&J transitioned to a Chinese talc source, the ore no longer required flotation to meet J&J’s specifications.” *See* 2020.06.04 - Hopkins Declaration and Exhibits, p. 7. After this transition, talc sourced from China had various names, including “Olympic H,” “Grade 25 USP,” and “Grade 25 NS.”
- [7] According to Dr. Hopkins, in 1990, J&J acquired a new XRD machine that was more sensitive than the equipment at ES Labs, so J&J performed the quarterly XRD testing of its finished talc. *See* 2020.06.04 - Hopkins Declaration and Exhibits; 1990.03.02 - DX8116.
- [8] J&J decided to test samples on a weekly basis as early as January 1972. *See, e.g.*, 1972.03.20 - DX8697. According to Dr. Hopkins, “the weekly samples of finished talc were combined to form biweekly composite samples.” *See* 2020.06.04 - Hopkins Declaration and Exhibits, p. 5; 1979.01.03 - JNJ000266695. According to Dr. Hopkins, from May 1973 to December 1975, J&J analyzed finished talc by XRD and DTA. From 1976 to 1987 and again from at least 1991 to 1993, J&J analyzed its finished talc by XRD, CTFA J4-1 (a two-step test involving XRD and PLM), and DTA. From 1981 to 1987, J&J continued to analyze its finished talc using CTFA J4-1, but discontinued internal testing by DTA. *See* 2020.06.04 - Hopkins Declaration and Exhibits; 1976.10.07 - DX7131; 1982.10.14 - JNJ 000266679.
- [9] According to Dr. Hopkins, “[f]rom 1987 through 1990, ES Labs routinely examined finished talc for Johnson & Johnson in the form of weekly, biweekly, triweekly, monthly and quarterly milled talc composite samples.” *See* 2020.06.04 - Hopkins Declaration and Exhibits, p. 6; 1987.02.27 -
- [10] According to Dr. Hopkins, “[f]rom 1993 to 2003, [IMERYS] tested biweekly or monthly composites of finished talc by XRD and PLM.” *See* 2020.06.04 - Hopkins Declaration and Exhibits, p. 7; Undated - DX8917. *See also* “Imerys Makes Binding Offer and Enters Exclusive Discussions With Rio Tinto for the Acquisition of the Luzenac Talc Group,” PRNewswire, February 23, 2011, available at <https://www.prnewswire.com/news-releases/imerys-makes-binding-offer-and-enters-exclusive-discussions-with-rio-tinto-for-the-acquisition-of-the-luzenac-talc-group-116717179.html>.
- [11] According to Dr. Hopkins, “[f]rom 2009 through at least 2018, Imerys tested monthly composites of milled Grade 25 talc, which does not go through a flotation process like Vermont talc, by J4-1 and TEM.” *See* 2020.06.04 - Hopkins Declaration and Exhibits, p. 7; Undated - DX8917.
- [12] According to Dr. Hopkins, “RJ Lee also tested talc samples representing every combination of mine and milling site in use globally. RJ Lee’s quarterly testing continues today and is meant to provide an added layer of confidence and assurance to the routine testing performed by J&J’s supplier.” *See* 2020.06.04 - Hopkins Declaration and Exhibits; 2009.08.28 - DX8716.
- [13] According to Dr. Hopkins, J&J occasionally engaged additional testers to perform additional methods of testing. In 1975 and 1976, the McCrone Group tested the samples using TEM. In 1976-1978 and 1981, EMV Associates tested the samples using SEM. *See* 2020.06.04 - Hopkins Declaration and Exhibits, p. 7; Undated - DX7483.
- [14] According to Dr. Hopkins, J&J’s testing method varied by year. In 1975-1976, J&J used XRD and DTA. In 1977-1985, J&J used XRD, PLM, and Optical Testing. In 1993-1996 and 1998-1999, J&J used Optical Testing. *See* 2020.06.04 - Hopkins Declaration and Exhibits, p. 7; Undated - DX7483.

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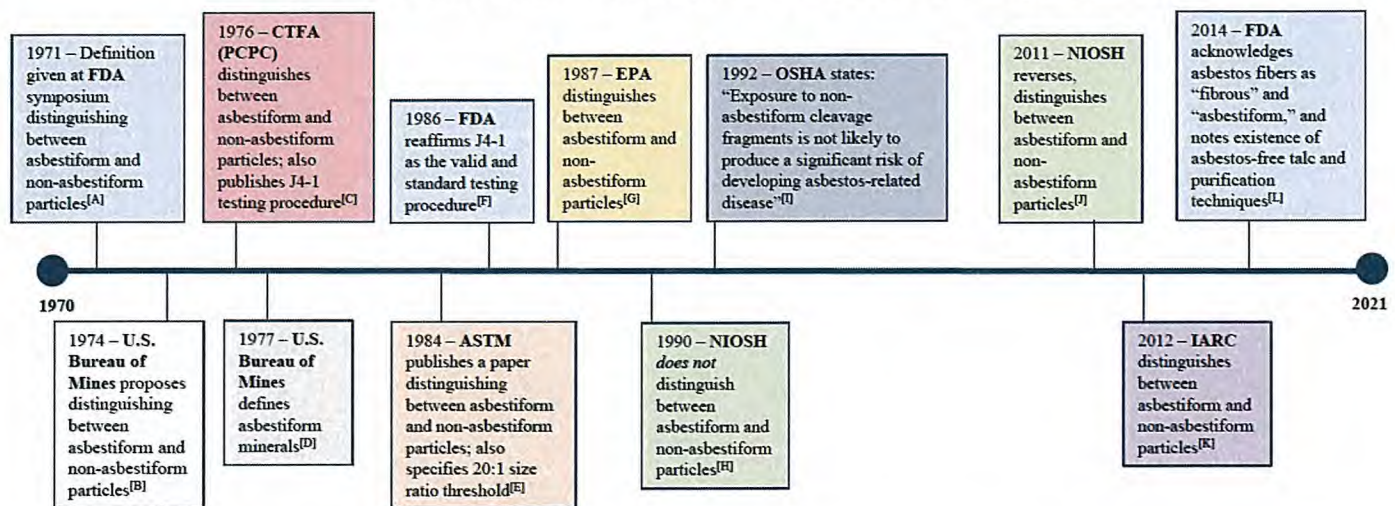
Figure 3
Timeline of Routine Testing of Johnson & Johnson's U.S. Cosmetic Talc Supply

Sources:

- [A] *See* 2020.06.04 - Hopkins Declaration and Exhibits.
- [B] *See* Appendix D, pp. 2-3. *See also* 2020.06.04 - Hopkins Declaration and Exhibits; 1978.02.23 - DX7147; 1978.11.14 - DX7149; 1978.12.08 - DX8378; 1994.01.10 - DX8411.
- [C] *See* Appendix D, pp. 4-5. *See also* 2001.05.17 - DX8701; 2020.06.04 - Hopkins Declaration and Exhibits.
- [D] *See* Appendix D, pp. 6-7. *See also* 2019 - JNJ TALC001282315 at 318; DX8917.
- [E] *See* Appendix D, pp. 8-9. *See also* 2020.06.04 - Hopkins Declaration and Exhibits; 1972.03.20 - DX8697; 1976.10.07 - DX7131; 1979.01.03 - JNJ000266695; 1990.03.02 - DX8116; 1982.10.14 - JNJ 000266679.
- [F] *See* Appendix D, pp. 10-11. *See also* 1987.02.27 - DX7522; 1983 - DX7484.
- [G] *See* Appendix D, pp. 12-13, 18-19. *See also* 2019 - JNJ TALC001282315 at 318; Undated - DX8917.
- [H] *See* Appendix D, pp. 14-17. *See also* 1977.02.15 - DX8561; 1995.02.14 - DX8135, 1999.11.01 - DX8523, 1999.05.12 - DX8524, 2000.03.15 - DX8526, 2000.02.14 - DX8525, 2001.05.17 - DX8701.
- [I] *See* Appendix D, pp. 20-21. *See also* 2019 - JNJ TALC001282315 at 318; 2020.06.04 - Hopkins Declaration and Exhibits; 2010.03.29 - DX7435.
- [J] *See* Appendix D, pp. 22-23. *See also* Undated - DX7483.

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Figure 4
Timeline of Industry Definitions of Asbestiform Particles and Testing Procedures

**Notes:**

[1] CTFA changed its name to the Personal Care Products Council (PCPC) in 2007. See “CTFA Changes Name to the Personal Care Products Council, Launches Consumer Information Web Site on Product Safety,” November 29, 2007, available at <https://www.personalcarecouncil.org/news-release/ctfa-changes-name-to-the-personal-care-products-council-launches-consumer-information-web-site-on-product-safety/>.

[2] Although companies and individuals have a legal responsibility to ensure the safety of cosmetics they manufacture and/or market, the law and the FDA do not require specific safety tests nor do they require reporting of safety information to the FDA. See “FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated,” FDA, July 24, 2018, available at https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated#Who_is_responsible. However, J&J has worked closely with the FDA regarding cosmetic talc safety for several decades and FDA Commissioner Scott Gottlieb described the test methods employed by J&J as “the most sensitive techniques available.” See 2019.03.05 – DX8029; see also Figure 3.

Sources:

[A] 1971.08.03 – DX7013 at 2 (Dr. Ross of the US Geological Survey).

[B] Robert Clifton, “Asbestos,” Bureau of Mines Minerals Yearbook: Metals, Minerals, and Fuels, 1974.

[C] 1976.10.07 – DX7131 at 9 (CTFA Method J4-1 – Asbestiform Amphibole Minerals in Cosmetic Talc).

[D] Campbell, William et al., “Selected Silicate Minerals and Their Asbestiform Varieties,” U.S. Bureau of Mines Information Circular 8751 (1977).

[E] Ross, Malcom, Richard A. Kuntze, and Robert A. Clifton, “Definition for Asbestos,” 1984, USGS Publications Warehouse.

[F] 1986.07.11 – DX7214 (1986 FDA Citizen Petition Response).

[G] 40 C.F.R. § 763.83.

[H] “NIOSH comments to DOL on the Occupational Safety and Health Administration’s notice of proposed rulemaking on occupational exposure to asbestos, tremolite, anthophyllite, and actinolite,” 1990.

[I] 57 Fed. Reg. 23410 (June 8, 1992).

[J] 2011.04 – DX9315 at vii (NIOSH Current Intelligence Bulletin 62: Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research)

[K] “IARC Monographs: Arsenic, Metals, Fibres, and Dusts: A Review of Human Carcinogens,” World Health Organization, Vol. 100C, 2012. See, e.g., p. 221.

[L] 2014.04.01 – DX7456 (2014 FDA Citizen Petition Response).

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Appendix A Curriculum Vitae

KATHLEEN M. SUTCLIFFE

Johns Hopkins University
100 International Drive
Baltimore, MD 21202
410.234.9442 (office)
ksutcliffe@jhu.edu

EDUCATION

PhD 1991, Organization Theory and Behavior, University of Texas, Austin, Texas
MN 1981, Community Health Systems, University of Washington, Seattle, Washington
BS 1978, Nursing Science, University of Alaska, Anchorage, Alaska
AB 1971, Education, University of Michigan, Ann Arbor, Michigan

ACADEMIC APPOINTMENTS

- Johns Hopkins University, Carey Business School, School of Medicine, School of Nursing, Bloomberg School of Public Health
 - Bloomberg Distinguished Professor, 6/2014-present
 - Faculty Fellow Armstrong Institute, 2014-present
- Ross School of Business, University of Michigan
 - Gilbert and Ruth Whitaker Professor Emerita of Business Administration, 6/2014-present
 - Professor Emerita of Management and Organizations, 6/2014-present
 - Gilbert and Ruth Whitaker Professor of Business Administration, 9/2006 – 6/2014
 - Associate Dean for Faculty Development and Research, 7/2006 – 6/2010
 - Professor of Management and Organizations, 9/2005 – 6/2014
 - Associate Professor of Organizational Behavior and Human Resource Management, 9/2001 – 8/2005
 - Assistant Professor of Organizational Behavior and Human Resource Management, 9/1994 – 8/2001
 - NBD Bancorp Assistant Professorship, 1996 - 1997
 - Faculty Fellow Tauber Manufacturing Institute, 1996 - 1998
- University of Minnesota Carlson School of Management
 - Assistant Professor of Organizational Behavior, 9/1991-8/1994

PUBLICATIONS

Books

Committee on Emerging Trends in Aviation Safety (National Academies of Science, Engineering and Medicine TRB). 2022. **Emerging Hazards in Commercial Aviation: Initial Assessment of Safety Data and Analysis Process**. Washington, DC: The National Academies Press.

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Sutcliffe, K.M., & Vogus, T. 2003. Organizing for resilience. In K.S. Cameron, J.E. Dutton, & R.E. Quinn (Eds.), **Positive Organizational Scholarship**. San Francisco: Berrett-Koehler, 94-110.

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Weick, K.E., & Sutcliffe, K.M. 2000. High reliability: The power of mindfulness. **Leader to Leader**, 33-38. San Francisco: Drucker Foundation/Jossey-Bass.

Reprinted in 2002 in F. Hesselbein & R. Johnston (Eds.), **On High Performance Organizations**. San Francisco: Jossey-Bass.

Browning, L. D., Sutcliffe, K. M., Sitkin, S., Obstfeld, D. & Greene, R. 2000. Keep 'em flying: The constitutive dynamics of an organizational change in the U. S. Air Force. **Electronic Journal of Communication/La Revue Electronique de Communication (EJC/REC)**, Vol. 10(1).

Sutcliffe, K.M. 2000. Motivational preconditions and intra-organizational barriers to learning in organizational settings. In T. Lant & Z. Shapira (Eds.), **Managerial and Organizational Cognition**. Mahwah, NJ: Lawrence Erlbaum, 147-153.

Sutcliffe, K.M., Sitkin, S.B., & Browning, L. 1999. Tailoring process management to situational requirements. Beyond the control and exploration dichotomy. In R. Cole & R. Scott (Eds.) **The Quality Movement and Organizational Theory**. Thousand Oaks, CA: Sage, 315-331.

Browning, L., Sutcliffe, K.M., Sitkin, S.B., Obstfeld, D., & Shetler, J. 1999. Task effectiveness and the implementation of process methods: Organizations in the dual pursuit of control and learning. In M. Beyerlein (Ed.), **Advances in the Interdisciplinary Studies of Work Teams**. Greenwich, CT: JAI, 203-245.

Vodosek, M., & Sutcliffe, K.M. 1999. Overemphasis on analysis: Decision making dilemmas in the age of speed. In R.E. Quinn, L. St. Clair, & R.M. O'Neill (Eds.), **The Pressing Problems of Modern Organizations: Transforming the Agenda for Research and Practice**. San Francisco: The New Lexington Press, 153-174.

Sitkin, S.B., Sutcliffe, K.M., & Weick, K.W. 1998. Organizational learning. In R. Dorf (Ed.), **The Technology Management Handbook**. Boca Raton, FL: CRC Press, Chap. 7, 70-76.

Confidential

Sutcliffe, K.M., Sitkin, S.B., & Browning, L.D. 1997. Perspectives on process management: Implications for research on 21st century organizations. In C. Cooper & S. Jackson (Eds.), **Creating Tomorrow's Organizations: A Handbook for Future Research in Organizational Behavior**. New York: John Wiley, 207-230.

Sutcliffe, K.M. 1997. The nuances of learning. In J. Walsh & A. Huff (Eds.), **Advances in Strategic Management**. Greenwich, CT: JAI, 331-336.

Huber, G.P., Sutcliffe, K.M., Miller, C.C. & Glick, W.H. 1993. Understanding and predicting organizational change. In G. Huber & W. Glick (Eds.), **Organizational Change and Redesign: Ideas and insights for improving managerial performance**. New York: Oxford University Press.

Refereed Proceedings

Sutcliffe, K.M., & Weick, K.E. 1999. The reduction of medical error through systemic mindfulness. Conference Proceedings, **Enhancing Patient Safety and Reducing Errors in Health Care**: 147-151.

Bunderson, J.S. & Sutcliffe, K.M. 1995. Work history and selective perception: Fine-tuning what we know. **Academy of Management Best Papers Proceedings**: 458-464.

McEvily, S., Sutcliffe, K.M., & Marcus, A. 1994. Explaining preferences for public policy: Strategic and contextual determinants. **Academy of Management Best Papers Proceedings**: 319-323.

Technical Reports

Huber, G.P., Glick, W.H., Miller, C.C., Doty, D.H., and Sutcliffe, K.M. This series of technical reports describes the research design, methodology, and instrumentation of the Changes in Organization Design and Effectiveness project, University of Texas. Order of authorship varies.

REFEREED CONFERENCE PAPERS AND INVITED PRESENTATIONS

Sutcliffe, K.M. 2024. Staying the course: Resilience insights from Adventure Racing. Invited speaker Kenan Institute Fellow lecture, University of North Carolina, March, Chapel Hill, NC.

Sutcliffe, K.M. 2024. What are high reliability organizations and high reliability organizing? Invited speaker conference on high reliability, National Institute of Justice, Office of Investigative and Forensic Sciences, January, Washington, DC.

Sutcliffe, K.M. 2024. Still not safe. Invited speaker UK National Health Service Safety Specialists Meeting, January (virtual).

Sutcliffe, K.M. 2023. Organizational errors: Updating the research agenda. 83rd Annual Meetings of the Academy of Management, August, Boston, MA.

Abernathy, J.H., Boss, E.F., Koka, R., Mayo, A., Myers, C.G., Najjar, P., Rosen, M.A., Suffredini, G.C., Sutcliffe, K.M., Yuan, C.T. 2023. Temporary multiteam systems. 83rd Annual Meetings of the Academy of Management, August, Boston, MA.

Dionysiou, D., Tsoukas, H. & Sutcliffe, K.M. 2023. Tasks and routines in organizations and institutions. 83rd Annual Meetings of the Academy of Management, August, Boston, MA.

Sutcliffe, K.M. 2023. Quality and safety: Glancing back and looking forward. Invited Grand Rounds Speaker Johns Hopkins Dept. of GYN-OB, March, Baltimore, MD.

Confidential

Sutcliffe, K.M. 2023. Organizational resilience: Some leadership basics. Invited speaker University of Florida Gainesville School of Medicine, March, Gainesville, FL.

Sutcliffe, K.M. 2023. Scholarship of problems and the problems of scholarship. Invited speaker Washington State University SON-Collaboration for Interprofessional Health Education Research & Scholarship (CIPHERS) ASPEN Mentoring Seminar Series, February (virtual).

Sutcliffe, K.M. 2022. Invited discussant for symposium titled "Relationships and resilience in the COVID-19 Pandemic". 82nd Annual meetings of the Academy of Management, August. Seattle, WA.

Sutcliffe, K.M. 2022. Invited discussant for symposium titled "Organizing for resilience: How to organize in a world of adversity and flux". 82nd Annual meetings of the Academy of Management, August. Seattle, WA.

Sutcliffe, K.M. 2022. Invited discussant for symposium titled "Practice perspectives on grand challenges: Insights from SAP and routine dynamics research". 82nd Annual meetings of the Academy of Management, August. Seattle, WA.

Sutcliffe, K.M. 2022. Patient safety's future through the lens of an organization scientist. Invited speaker Julius Scher Lecture, Jefferson Health System, April, Philadelphia, PA.

Sutcliffe, K.M. 2022. Organizational resilience: Some leadership basics. Invited speaker The Navy Lewis E. Angelo Professional Symposium (LEAPS) at the annual meeting of the American College of Health Care Executives, March, Chicago, IL.

Sutcliffe, K.M. 2022. Organizational theory and health care. Invited seminar Interdisciplinary Consortium on Organization Studies (ICOS) University of Michigan, January, Ann Arbor, MI.

Sutcliffe, K.M. 2021. Organizational resilience: Some academic basics. Invited speaker pediatric grand rounds Johns Hopkins University School of Medicine, December, Baltimore, MD. (virtual)

Sutcliffe, K.M. 2021. Patient safety through the lens of an organizational theorist. Invited speaker, Human Factors in Patient Safety Inaugural Conference, Royal College of Surgeons in Ireland (RCSI), September. (virtual)

Sutcliffe, K.M. 2021. A more nuanced view of crisis theorizing. Panelist in session "Facing the profitability-people dilemma during a crisis". 81st Annual meetings of the Academy of Management, August. (virtual)

Sutcliffe, K.M. 2021. Invited discussant for symposium titled Understanding the workplace consequences of uncertainty through the lens of Covid-19. 81st Annual meetings of the Academy of Management, August. (virtual)

Sutcliffe, K.M. 2021. Crises, expectations, and entrepreneurs. Panelist in session "Adaptation, learning and survival during an unprecedented shock: The pandemic and entrepreneurship". 81st Annual meetings of the Academy of Management, August. (virtual)

Sutcliffe, K.M. 2021. Patient safety's future through the lens of an organization scientist. Invited speaker, Stanford Medicine Center for Improvement, June, San Francisco, CA (virtual)

Sutcliffe, K.M. 2021. High reliability organizing and the next wave of innovation in patient safety. Invited speaker, Massachusetts General Hospital and Clinics, April, Boston, MA (virtual).

Confidential

Sutcliffe, K.M. 2021. The next wave of innovation in patient safety. Invited speaker Health Services Resource Administration (HRSA), March, Washington, DC (virtual).

Sutcliffe, K.M. 2021. Organizational resilience: Academic basics and organizing implications. Invited speaker combined anesthesiology/surgery grand rounds, Johns Hopkins University School of Medicine, February, Baltimore, MD (virtual).

Sutcliffe, K.M. 2021. The next wave of innovation in patient safety. Invited speaker Trinity Health System, February, Southfield, MI (virtual).

Sutcliffe, K.M. 2020. Stepping into uncertainty: Taking stock and setting a future research agenda. Invited discussant for paper session "Uncertainty in management research." Annual meetings of the Southern Management Association of the AOM, October, St. Petersburg, FL (virtual).

Sutcliffe, K.M. 2020. Organizing for high reliability. Invited presentation Embry-Riddle Aeronautical University, August, FL (virtual).

Sutcliffe, K.M. 2020. The role of organizing in extreme contexts. Co-convenor and speaker with M. Hallgren & M. de Rond, Annual Meetings of the European Group on Organization Studies, July, Hamburg, Germany (virtual).

Sutcliffe, K.M. 2020. Coping and resilience during Covid-19. Invited presenter in "AOM-MOC thinking about..." series, May, cohosted by John Hopkins Carey Business School, Baltimore (virtual).

Sutcliffe, K.M. 2019. Organizational resilience: Academic basics and organizing implications. Invited keynote speaker (Think@Ashburn evening), George Washington University, Human and Organizational Learning, December, Washington, DC.

Sutcliffe, K.M. 2019. Achieving a culture of safety. Annual meetings of the Society for Risk Analysis, December, Arlington, VA.

Sutcliffe, K.M. 2019. On the knife's edge: Lessons from corporate America for the OR. Invited presentation to Johns Hopkins University Board of Trustees, December, Baltimore, MD.

Sutcliffe, K.M. 2019. The next wave of innovation to keep patients safe. Invited keynote speaker Maryland Patient Safety Center, October, Anne Arundel County, MD.

Sutcliffe, K.M. 2019. High reliability organizing: A crash course. Invited speaker Healthcare Event Reporting Collaborative Meeting, October, Baltimore, Armstrong Institute.

Sutcliffe, K.M. 2019. Managing the unexpected: Resilience in an age of uncertainty. Invited keynote speaker, University of Alaska Anchorage Homecoming Breakfast, October, Anchorage, AK.

Sutcliffe, K.M. 2019. The next wave of innovation to keep patients safe. Invited keynote speaker 16th annual multidisciplinary Cardiovascular and Thoracic Critical Care Conference, Society for Thoracic Surgeons, September, Baltimore, MD.

Sutcliffe, K.M. 2019. Organizational resilience: Some academic basics. Invited keynote speaker Robson Conference on Resilience, Emory University and The Carter Center, September, Atlanta, GA.

Sutcliffe, K.M. 2019. Invited discussant for paper session "Searching for social order in extreme contexts." Annual meetings of the Academy of Management, August, Boston, MA.

Confidential

Dionysiou, D. & Sutcliffe, K.M. 2019. Unpacking organizational routines. Paper presentation at the Annual meetings of the Academy of Management, August, Boston, MA.

Sutcliffe, K.M. and Hoff, T. 2019. Facilitator Hot topics in healthcare management research. Annual meetings of the Academy of Management, August, Boston, MA.

Sutcliffe, K.M. 2019. Facilitator Cognition in the Rough Workshop. Annual meetings of the Academy of Management, August, Boston, MA.

Sutcliffe, K.M. 2019. Reflections on patient safety. Invited speaker 2nd Johns Hopkins Symposium on Healthcare Operations, April, Baltimore, MD.

Sutcliffe, K.M. 2019. The next wave of innovation in patient safety. Invited keynote speaker, Johns Hopkins Bayview Patient Safety Summit, March, Baltimore, MD.

Sutcliffe, K.M. 2018. Scholarship of problems and the problems of scholarship. Invited keynote speaker, University of Texas Annual PhD Conference, November, Austin, TX.

Sutcliffe, K.M. 2018. Patient safety through the lens of an organizational theorist. Invited speaker JHU Provost's Bloomberg Professors Speakers Series, November, Baltimore, MD.

Sutcliffe, K.M. 2018. Basics of leading change. Invited speaker US Secretary of the Navy, November, Pentagon City, Washington DC.

Sutcliffe, K.M. 2018. Organizing for resilience. Invited keynote speaker Suburban Hospital Patient Safety and quality Forum, November, Bethesda, MD.

Sutcliffe, K.M. 2018. High reliability organizing. Invited keynote speaker, Kaiser-Permanente Leadership Development Institute, August, Riverside, CA.

Sutcliffe, K.M. 2018. Invited discussant for paper session "Errors in Organizations." Annual meetings of the Academy of Management, August, Chicago, IL.

Sutcliffe, K.M. 2018. Invited discussant for paper session "Positive Emotions." Annual meetings of the Academy of Management, August, Chicago, IL.

Sutcliffe, K.M. 2018. Prospective sensemaking in organizations. Presentation at the annual meetings of the Academy of Management, August, Chicago, IL.

Sutcliffe, K.M. 2018. Revisiting trust: New reviews, directions and emergent challenges. PDW presentation at the annual meetings of the Academy of Management, August, Chicago, IL.

Sutcliffe, K.M. 2018. Resilience in action. Invited keynote speaker, Council for Advancement and Support in Education Annual Conference, June, Alexandria, VA.

Sutcliffe, K.M. 2018. Organizing for reliability in healthcare. Invited keynote speaker, Munson Healthcare, June, Traverse City, MI.

Sutcliffe, K.M. 2018. Resilience in healthcare. Invited speaker, Frontiers in Patient Safety Conference, Centre for Quality, University of Southern Denmark, April, Odense, Denmark.

Sutcliffe, K.M. 2018. Organizational mindfulness: A reflection. Invited speaker, Witten/Herdecke University Mindful Leadership Conference, March, Stuttgart, Germany

Sutcliffe, K.M. 2018. Resilience in (inter)action. Invited speaker, Duke-Fuqua School of Business, February, Raleigh-Durham, NC.

Sutcliffe, K.M. 2018. Organizational resilience. Invited keynote speaker, International Conference on Infrastructure Resilience, ETH University, February, Zurich, Switzerland.

Sutcliffe, K.M. 2018. High reliability organizing and patient safety. Invited speaker UniversitätsSpital Zürich, February, Zurich, Switzerland.

Sutcliffe, K.M. 2018. The next wave of innovation to make patients safe. Invited panelist/speaker, 2018 Society for Thoracic Surgeons annual meeting, January, Fort Lauderdale, FL.

Sutcliffe, K.M. 2018. Resilience in inter-action. Invited speaker University of Toronto Rotman School of Business, January, Toronto, Canada.

Sutcliffe, K.M. 2017. High reliability organizing: A model for patient safety. Invited key note speaker, 2017 Carilion Quality Conference, December, Roanoke, VA.

Sutcliffe, K.M. 2017. Perspectives on risk, safety, and resilience. Invited panelist/speaker, Society for Risk Analysis Annual Meeting, December, Arlington, VA.

Sutcliffe, K.M. 2017. High reliability organizations. Invited key note speaker, Sibley Patient Safety Forum, Sibley Memorial Hospital, November, Washington DC.

Sutcliffe, K.M. 2017. Resilience-in-(inter)-action. Invited keynote speaker, Risk – Resilience Festival, University of Twente, November, Enschede, Netherlands.

Sutcliffe, K.M. 2017. Women in STEM. Invited discussant Broadening perspectives on women in work: An interdisciplinary conference, Johns Hopkins Carey Business School, October, Baltimore, MD.

Sutcliffe, K.M. 2017. Habits for high reliability. Invited moderator and panelist Johns Hopkins Medicine Eighth Annual Patient Safety Summit, October, Baltimore, MD.

Sutcliffe, K.M. 2017. HROs a spirited history and roads ahead. Invited keynote speaker, 2017 High Reliability Summit, September, Washington DC.

Barton, M., & Sutcliffe, K.M. 2017. Making the case for relational resilience: A study of expedition racing. Paper presentation at the annual meeting of the Academy of Management, August, Atlanta, GA.

Sutcliffe, K.M. 2017. Revisiting trust: New reviews, directions and emergent challenges. PDW paper presentation at the annual meetings of the Academy of Management, August, Atlanta, GA.

Barton, M., & Sutcliffe, K.M. 2017. Contextualized engagement as resilience-in-action: A study of expedition racing. Paper presentation at the annual meeting of EGOS, July, Copenhagen, Denmark.

Sutcliffe, K.M., Meyers, C., Frimpong, J., Paine, L., & Rosen, M. 2017. Strengthening culture at JHH: Inquiry versus advocacy. Invited speakers Johns Hopkins Medicine Multidisciplinary Grand Rounds. March, Baltimore, MD.

Sutcliffe, K.M. 2017. Managing the unexpected. Invited keynote speaker Johns Hopkins University Rising to the Challenge Development Alumni Relations Leadership Conference. March, Baltimore, MD.

Confidential

Sutcliffe, K.M. 2016. High reliability healthcare. Invited keynote speaker Northwestern University Medicine Improvement Day. November, Chicago, IL.

Sutcliffe, K.M. 2016. High reliability healthcare. Invited keynote speaker World Health Organization Setting Priorities for Global Patient Safety Conference. September, Florence, Italy.

Sutcliffe, K.M., & Meyers, C. 2016. Strengthening culture at JHH: Trust, communication and handoffs. Invited speakers Johns Hopkins Medicine Multidisciplinary Grand Rounds. September, Baltimore, MD.

Sutcliffe, K.M. 2016. Power, sensemaking and organizing. Co-convenor and speaker with S. Maitlis & G. Patriotta for EGOS conference. July, Naples, Italy.

Sutcliffe, K.M. 2016. Compassion practices, nurse well-being and ambulatory patient experience ratings. Invited discussant at the annual meeting of the Organizational Theory in Healthcare Association. June, Nashville, TN.

Sutcliffe, K.M. 2016. Building a resilient organization. Invited keynote speaker Johns Hopkins Carey Business School Global Health Care Symposium-Pursuing Productive Care. March, Shanghai, China.

Sutcliffe, K.M. 2016. Managing the unexpected. Invited keynote speaker Georgia Pacific Process Safety Annual Conference, February, Atlanta, GA.

Sutcliffe, K.M. 2016. Transforming culture. Invited keynote speaker Johns Hopkins High Reliability Healthcare Summit. February, Baltimore, MD.

Sutcliffe, K.M. 2016. High reliability organizing. Invited keynote speaker Johns Hopkins High Reliability Healthcare Summit. February, Baltimore, MD.

Sutcliffe, K.M. 2016. Transforming culture. Invited keynote speaker Johns Hopkins High Reliability Healthcare Summit. February, Dhahran, Saudi Arabia.

Sutcliffe, K.M. 2016. High reliability organizing: A model for patient safety. Invited keynote speaker Johns Hopkins Aramco Healthcare Patient Safety Symposium. February, Dhahran, Saudi Arabia.

Sutcliffe, K.M. 2015. Organizing for high reliability in health care. Invited keynote speaker Air Force Medical Service Senior Leadership Conference, November, Leesburg, VA.

Sutcliffe, K.M. 2015. Managing the unexpected. Invited keynote speaker Georgia Pacific Process Safety Knowledge Share Conference, September, Atlanta, GA.

Gruber, D., & Sutcliffe, K.M. 2015. Repositioning crisis management: The role of resilience. Symposium organizers for the Annual Meetings of the Academy of Management, August, Vancouver, BC.

Sutcliffe, K.M. 2015. MOC scholar reflections. Invited keynote (MOC Scholar Award and Address) at the Annual Meetings of the Academy of Management, August, Vancouver, BC.

Sutcliffe, K.M. 2015. High reliability organizing: A model for patient safety. Keynote speaker SCL Health System/State of CO Patient Safety Conference, June, Denver, CO.

Sutcliffe, K.M. 2015. Transforming culture. Keynote speaker SCL Health System/State of CO Patient Safety Conference, June, Denver, CO.

Sutcliffe, K.M. 2015. High reliability organizing: A model of patient safety. Keynote speaker SCL Health System/State of CO Patient Safety Conference, June, Denver, CO.

Confidential

Sutcliffe, K.M. 2015. Organizational change and transformation. Keynote speaker Barnes Jewish Patient Safety Conference, February, St. Louis, MO.

Sutcliffe, K.M. 2015. High reliability organizing: A model for patient safety. Keynote speaker Barnes Jewish Patient Safety Conference, February, St. Louis, MO.

Sutcliffe, K.M. 2014. Transforming culture. Keynote speaker Johns Hopkins Medicine Leadership Conference, October, Baltimore, MD.

Sutcliffe, K.M. 2014. Leadership and safety culture. Invited expert testimony at the Defense Nuclear Facilities Safety Board Safety Culture Public Meeting and Hearing, August 23, Washington DC.

Dionysiou, D. & Sutcliffe, K.M. 2014. Perceptual uncertainty and the creation and evolution of routines. Paper presentation at the Annual Meetings of the Academy of Management, August, Philadelphia, PA.

Sutcliffe, K.M. & DeWitt, T. 2014. Weak signals, sensemaking, and learning. Paper presentation at the Annual Meetings of the Academy of Management, August, Philadelphia, PA.

Sutcliffe, K.M. 2014. Performing under uncertainty: Contextualized engagement in wildland firefighting. Paper presentation Annual Meetings of EGOS, July, Rotterdam, Netherlands.

Sutcliffe, K.M. 2014. High reliability organizing as a model for patient safety. Keynote speaker St. John Providence Health System Research Day, May, Southfield, MI.

Sutcliffe, K.M. 2014. High reliability organizing as a model for patient safety. UM Patient Safety and Quality Leadership Scholars Program. April, University of Michigan, Ann Arbor, MI.

Sutcliffe, K.M. 2014. Enabling fluid awareness for resilient performance. Invited speaker VA National Center for Patient Safety, April, Ann Arbor, MI.

Sutcliffe, K.M. 2014. Sensemaking and resilient performance. Invited speaker The Eighth International High Reliability Organizing Conference, March, Fort Worth, TX.

Sutcliffe, K.M. 2014. Enabling fluid awareness for resilient performance. Invited speaker Swiss Federal Nuclear Safety Inspectorate international conference on human performance under extreme conditions with respect to a resilient organization, February, Brugg, Switzerland.

Sutcliffe, K.M. 2013. Culture and safety: The role of high reliability organizing. Healthcare Administration Scholars Program, University of Michigan Medical School, October, Ann Arbor, MI.

Sutcliffe, K.M. 2013. Mindful organizing to patient safety. Invited speaker Johns Hopkins University, October, Baltimore, MD.

Sutcliffe, K.M. 2013. High reliability organizing: A model for patient safety. Keynote speaker patient safety conference, Tri City Medical, San Diego, CA.

Sutcliffe, K.M. 2013. Resilience and patient safety: High reliability organizing as a model. UM Patient Safety and Quality Leadership Scholars Program. University of Michigan, Ann Arbor, MI.

Sutcliffe, K.M. 2013. High reliability organizing and patient safety. Keynote speaker Grand Rounds Medstar Health, Columbia, MD.

Sutcliffe, K.M. 2012. Organizing for reliability: Pathways of safer care. Keynote speaker Veterans Health Administration NE Nurse Executive Annual Meeting, Portland, ME.

Confidential

Sutcliffe, K.M. 2012. Routines in hot situations: The role of routines in handling crisis. Discussant for paper session at the Annual Meetings of the Academy of Management, Boston, MA.

Sutcliffe, K.M. 2012. Overload in hospitals: Theory and its application to improve patient safety. Paper presentation at the Annual Meetings of the Academy of Management, Boston, MA.

Waller, M.J. & Sutcliffe, K.M. 2012. Adaptation to discontinuous nonroutine events: Dual threats and the mediator of fear. Paper presentation at the Annual Meetings of the Academy of Management, Boston, MA.

Sutcliffe, K.M. 2012. Managing for the unexpected/Organizing for resilience. Invited speaker International Atomic Energy Agency technical meeting on managing the unexpected from the perspective of the interaction between individuals, technology, and organization, Vienna, Austria.

Barton, M.A., Sutcliffe, K.M., Vogus, T.J. 2012. Enabling Fluid Organizational Awareness under Dynamic Uncertainty. Paper presentation at the Fourth International Symposium on Process Organization Studies, Kos, Greece.

Sutcliffe, K.M. 2012. Safety: Complex but manageable/Pathways to reliability. Invited speaker System Safety Society Meeting of Canada, Ottawa, Canada.

Sutcliffe, K.M. 2012. Outcome tradeoffs: Lessons from HROs. Invited speaker 2012 Fifth International (HRO) Conference: Seeking reliability through operations, attitudes, and measuring success, Chicago, IL.

Sutcliffe, K.M. 2012. Commentary on the evolution of HRO. Invited speaker Organizational Reliability conference. Vanderbilt University, Nashville, TN.

Sutcliffe, K.M. 2012. Organizing for mindfulness and high reliability. Invited speaker Ohio Childrens' Hospitals Collaboratory on Patient Safety, Cleveland, OH.

Sutcliffe, K.M. 2011. High reliability in healthcare: A call to action. Invited speaker Swiss Patient Safety Foundation Conference on Patient Safety. Basel, Switzerland.

Sutcliffe, K.M. 2011. Organizing for high reliability. Invited speaker HRO conference, The Hague University, Netherlands.

Sutcliffe, K.M. 2011. Mindful organizing for reliability: Pathways to resilience. Invited speaker University of Windsor, Ontario, Canada.

Sutcliffe, K.M. 2011. Transitions in understanding: Exploring how understanding evolves in dynamic contexts. Discussant for paper session at the annual meetings of the Academy of Management, San Antonio, TX.

Sutcliffe, K.M. 2011. Dilemmas of learning in organizations: Exploring negative effects of learning. Paper presentation at the annual meetings of the Academy of Management. San Antonio, TX.

Sutcliffe, K.M. 2011. The "medicalization" of patient safety: A sensemaking/sensegiving perspective. Paper presentation at the annual meetings of the Academy of Management. San Antonio, TX.

Sutcliffe, K.M. 2011. Invited speaker California Sanitation Risk Management Association, San Diego, CA.

Sutcliffe, K.M. 2011. Invited speaker US Department of the Interior University, Washington DC.

Confidential

Sutcliffe, K.M. 2011. Grand Rounds, DeVos Children's Hospital, Grand Rapids, MI.

Sutcliffe, K.M. 2011. Invited speaker, Veterans Health Administration Enterprise Risk Management Conference, Ann Arbor, MI.

Sutcliffe, K.M. 2011. Three studies on patient safety. Invited presentation to the Robert Wood Johnson Fellows, University of Michigan Medical School, Ann Arbor, MI.

Sutcliffe, K.M. 2011. From wildland firefighting to patient safety. MO brownbag presentation, University of Michigan, Ann Arbor, MI.

Sutcliffe, K.M. 2011. Invited speaker Ross Health and Life Sciences club/IHI open university, University of Michigan, Ann Arbor, MI.

Sutcliffe, K.M. 2011. Organizational resilience. Paper presentation at Resilience 2011, Arizona State University, Phoenix, AZ.

Sutcliffe, K.M. 2010. Mindfulness and organizational adaptation. Paper presentation at the 2010 INFORMS meeting, Austin, TX.

Sutcliffe, K.M. 2010. Invited speaker, The Canadian Healthcare Safety Symposium Halifax Series, Halifax, Nova Scotia, Canada.

Sutcliffe, K.M. 2010. Keynote speaker, Great Lakes Forest Fire Compact annual meeting, Lewiston, MI.

Sutcliffe, K.M. 2010. Grand Rounds, SUNY Stony Brook, Stony Brook, NY.

Vogus, T., Sutcliffe, K.M., Weick, K.E. 2010. Doing no harm: Enabling, enacting, and elaborating a culture of safety in health care. Paper presentation at the 2010 annual meetings of the Academy of Management, Montreal, Quebec, Canada.

Sutcliffe, K.M. 2010. Invited presentation to the FDNY Commissioner and Chiefs, New York City.

Sutcliffe, K.M. 2010. Grand Rounds, Cincinnati Children's Hospital and Medical Center/University of Cincinnati Medical School, OH.

Sutcliffe, K.M. 2010. Keynote panelist, Canadian Anesthesiology Society, Montreal Canada.

Sutcliffe, K.M. 2010. Invited speaker, European Society for Anaesthesiology, Helsinki, Finland.

Sutcliffe, K.M. 2010. Problem finding: Insights from HROs. Harvard SOE/Business School, Learning Innovations Conference, April, Boston, MA.

Sutcliffe, K.M. 2010. Keynote speaker, Agency for Healthcare Research and Quality HRO Consensus Conference, Washington DC.

Sutcliffe, K.M. 2010. Grand Rounds, New York University Medical School, Dept of Anesthesiology, NY, NY.

Sutcliffe, K.M. 2009. Organizing for resilience. Keynote speaker the Canadian Healthcare Safety Symposium 9: Human Performance and Healthcare Safety. Montreal, Canada.

Sutcliffe, K.M. 2009. Keynote speaker 14th Annual Mayo Clinic Conference on Quality, Safety and Service, Rochester, MN.

Confidential

Sutcliffe, K.M. 2009. Knowledge, expertise, creativity and innovation. Discussant for paper session at the annual meetings of the Academy of Management, Chicago, IL.

Stevens, F. & Sutcliffe, K.M. 2009. Cracks in top management teams. Paper presentation at the 2009 annual meetings of the Academy of Management, Chicago, IL.

Sutcliffe, K.M. 2009. Keynote speaker Michigan Society of Thoracic and Cardiovascular Surgeons, Traverse City, MI.

Sutcliffe, K.M. 2009. Keynote speaker International Symposium on Process Organization Studies: Sensemaking and Organizing, Pissouri, Cyprus.

Sutcliffe, K.M. 2009. Keynote speaker Health Services Research Day, University of Toronto, Toronto, Canada.

Sutcliffe, K.M. 2009. Keynote speaker Protecting our Patients, Protecting Ourselves: Recognizing the Human Factor in Patient Care, Philadelphia (Malvern), PA.

Sutcliffe, K.M. 2009. Mindful organizing and reliable performance: Implications from three studies. Invited presentation University of Houston Business School, Houston, TX.

Sutcliffe, K.M. 2009. Mindful organizing and reliable performance: Implications from three studies. Invited presentation Case Western Reserve Business School, Columbus, OH.

Sutcliffe, K.M. 2008. Keynote speaker, Safety Standdown (aviation industry conference), Kansas City, Mo.

Sutcliffe, K.M. 2008. Keynote speaker Human Factors in Healthcare: Practical Applications to Improve Patient Safety, Mayo Clinic, Rochester, MN.

Sutcliffe, K.M. 2008. The quest to resilience: Examining the role of emotions and relationships. Discussant for paper session annual meetings of the Academy of Management, Philadelphia, PA.

Sutcliffe, K.M. 2008. Information overload revisited. Paper presentation at the 2008 annual meetings of the Academy of Management, Anaheim, CA.

Barton, M. A., & Sutcliffe, K.M. 2008. Overcoming dysfunctional momentum. Paper presentation at the 2008 annual meetings of the Academy of Management, Anaheim, CA.

Sutcliffe, K.M. 2008. Organizing for resilience. Keynote speaker Beacon Collaborative, San Francisco, CA.

Sutcliffe, K.M. 2008. Organizing for resilience. Keynote speaker Hawaiian Medical Society, Honolulu, HI.

Sutcliffe, K.M. 2007. Organizing for resilience. Keynote speaker X Organisationen, Universitaet Witten/Herdecke, Berlin, Germany.

Sutcliffe, K.M. 2007. Keynote speaker, Safety Standdown (aviation industry conference), Wichita, KS.

Sutcliffe, K.M. 2007. The next generation: MOC best papers. Discussant for paper session annual meetings of the Academy of Management, Philadelphia, PA.

Confidential

Sutcliffe, K.M. 2007. Screams, SWAT teams, and states of emergency. Understanding organizational surprise. Discussant for paper session annual meetings of the Academy of Management, Philadelphia, PA.

Sutcliffe, K.M. 2007. Organizing for resilience. Invited speaker National Patient Safety Foundation Annual Conference, Washington DC.

Sutcliffe, K.M. 2007. Information overload revisited. Invited presentation ICOS, University of Michigan, Ann Arbor, MI.

Sutcliffe, K.M. 2006. To err is organizational: Reducing medical error through mindful organizing. Hosmer presentation, Ross School of Business, Ann Arbor, MI.

Sutcliffe, K.M. 2006. Mindful organizing and reliable performance in healthcare: Inferences from three studies. Invited presentation Harvard Business School, Boston, MA.

Sutcliffe, K.M. 2006. Keynote speaker, Safety Standdown (aviation industry conference), Wichita, KS.

Sutcliffe, K.M. 2006. Organizational resilience: A social mechanisms perspective. Discussant for paper session annual meetings of the Academy of Management, Atlanta, GA.

Sutcliffe, K.M., Spreitzer, G., Dekas, K. 2006. Beyond the bottom line: What really matters in organizations. All Academy symposium chair and paper presentation at the annual meetings of the Academy of Management, Atlanta, GA.

Sutcliffe, K.M. 2006. Using organizational culture theory and measures to guide change in the delivery of health care. Paper presentation at the 2006 annual meetings of the Academy of Management, Atlanta, GA.

Ashford, S.J., Sutcliffe, K.M., & Morrison, E.W. 2006. Pressures of position: Leadership and the problem of staying open to voice from below. Paper presentation at the 2006 annual meetings of the Academy of Management, Atlanta, GA.

Gruber, D., & Sutcliffe, K.M. 2006. Newsbreaking and sensemaking: An orienting analysis of theory and practice in newsrooms. All Academy symposium chair and paper presentation at the annual meetings of the Academy of Management, Atlanta, GA.

Sutcliffe, K.M. 2006. Organizing for resilience. Invited presentation, Michigan Difference Seminar (top donors to UM), University of Michigan, Ann Arbor, MI.

Sutcliffe, K.M. 2006. Situationally self-serving: The role of context in shaping executives' attributions. Invited presentation Kellogg School of Management, Northwestern University, Evanston, IL.

Sutcliffe, K.M. 2006. Mindfully organizing for safety. Paper presented at the Berkeley Conference on High Reliability Organizations, Ontario, CA.

Sutcliffe, K.M. 2006. Information acquisition, perceptual acuity and firm performance: A dynamic capabilities perspective. Hosmer Speaker Series, Ross School of Business at the University of Michigan.

Sutcliffe, K.M. 2006. Information acquisition, perceptual acuity and firm performance: A dynamic capabilities perspective. Invited presentation, Ivey Business School, London, Ontario, Canada.

Christianson, M., & Sutcliffe, K.M. 2005. Building capabilities: Reconceptualizing organizational resources. Symposium chair and paper presentation at the 2005 annual meetings of the Academy of Management, Honolulu, HI.

Confidential

Christianson, M.K., Spreitzer, G.M., Sutcliffe, K.M., & Grant, A.M. 2005. An empirical examination of thriving at work. Paper presented at the 2005 annual meetings of the Academy of Management, Honolulu, HI.

Sutcliffe, K.M. 2005. Organizing for resilience. Keynote speaker, CESSE Annual Meetings (Council of Engineering and Scientific Societies), Portland, OR.

Sutcliffe, K.M. 2005. Organizing for highly reliable performance in healthcare. Keynote speaker, Kaiser Permanente Perinatal Patient Safety Conference, San Francisco, CA.

Sutcliffe, K.M. 2005. Organizing for high reliability in healthcare. Invited presentation, INSEAD, Fontainebleau, France.

Sutcliffe, K.M. 2005. An empirical examination of thriving at work. Invited presentation, University of Illinois School of Business, Urbana Champaign, IL.

Sutcliffe, K.M. 2005. Executive information search, environmental perception and firm performance. Invited presentation, MIT Sloan School of Business, Boston, MA.

Sutcliffe, K.M. 2004. Organizing for high reliability performance in health care. Invited speaker, Trinity Health System Annual Conference: Leading, Healing, Transforming, Dearborn, MI.

Sutcliffe, K.M. 2004. Organizational underpinnings of patient safety: Organizing for resilience. Invited keynote speaker, Mayo Health System Patient Safety Forum: Leading the Way, Rochester, MN.

Christianson, M., Blatt, R., Sutcliffe, K.M. 2004. Relational dynamics of silence and voice: Lessons from medical error. Paper presented at the 2004 annual meetings of the Academy of Management, New Orleans, LA.

Sutcliffe, K.M. 2004. Collective competence in the emergency department: Mindfulness through heedful interrelating and heedful attending. Paper presented at the 2004 annual meetings of the Academy of Management, New Orleans, LA.

Sutcliffe, K.M. 2004. Organizing for resilience: The mechanisms of medical mistakes. Invited keynote speaker, Patient Safety Learning Pilots Centers for Medicare and Medicaid, Alexandria, VA.

Vogus, T., & Sutcliffe, K.M. 2003. Functional diversity versus requisite variety in top management teams. Strategic Management Society, Baltimore, MD.

Sutcliffe, K.M. 2003. Functional diversity versus requisite variety in top management teams. Invited presentation Michigan State University, East Lansing, MI.

Sutcliffe, K.M. 2003. Understanding the mechanisms of medical mistakes. Paper presented at the 2003 annual meetings of the Academy of Management, Seattle, WA.

Sutcliffe, K.M. 2003. Leadership: Social exchange, cognition, and attribution. Invited discussant annual meetings of the Academy of Management, Seattle, WA.

Sutcliffe, K.M. 2003. Cultures of entrapment: A reanalysis of the Bristol Royal Infirmary. Invited speaker Health Care Organizations Conference 5, University of Michigan School of Public Health, Ann Arbor, MI.

Sutcliffe, K.M. 2003. Managerial cognition. Invited speaker Stern School of Business, New York University. New York, NY.

Confidential

Sutcliffe, K.M. 2003. Organizing for the unexpected: Different challenges for information scholars. Invited speaker Katz School of Business University of Pittsburgh, Pittsburgh, PA.

Wears, R., Sutcliffe, K.M., & Perry, S., Murphy, L., Eisenberg, E., Strongbow, R., & Schenkel, S. 2003. Understanding errors in emergency departments. Paper presented at the 5th Annual NPSF Patient Safety Congress, Let's Get Results. Washington, DC.

Sutcliffe, K.M. 2002. Organizational underpinnings of medical errors: Organizing for resilience. Invited keynote speaker at the California Medical Association 6th Annual Leadership Academy, Palm Springs, CA.

Vogus, T. & Sutcliffe, K.M. 2002. Resilience processes in organizational behavior: A multi-level perspective. Paper presented at the 2002 annual meetings of the Academy of Management, Denver CO.

Sutcliffe, K.M., & Vogus, T. 2002. Organizing for resilience: Processes and prospects. Co-chair symposium presentation at the 2002 annual meetings of the Academy of Management, Denver CO.

Wooten, M., & Sutcliffe, K.M. 2002. The impact of race and gender on organizational effectiveness: Toward a more encompassing theory. Paper presented at the 2002 annual meetings of the Academy of Management, Denver CO.

Sutcliffe, K.M., Wears, R.L. 2002. Understanding errors in the emergency department. Annenberg IV Conference of the National Patient Safety Foundation. Indianapolis, IN.

Sutcliffe, K.M. 2001. Theories of organizational safety. Paper presented at the AHRQ funded conference titled Creating an organizational infrastructure for patient safety: Needs assessment, research base, and research opportunities. University of Michigan Business School, Ann Arbor, MI.

Sutcliffe, K.M., & Tamuz, M. 2001. To err is organizational: Blindspots in research on adverse medical events. Co-chair, symposium presentation at the 2001 annual meetings of the Academy of Management, Washington D.C.

Sutcliffe, K.M., Rosenthal, M., & Lewton, E. 2001. Insight in hindsight: Confronting challenges of studying medical mishaps in retrospect. Paper presented at the annual meetings of the Academy of Management, Washington D.C.

Vogus, T. & Sutcliffe, K.M. 2001. On the road to mindfulness: Requisite variety and firm performance. Refereed invited presentation at the Organizational Learning and Knowledge Management Conference, Ivey School of Business, University of Western Ontario, London, Ontario, Canada.

Sutcliffe, K.M. 2001. How medical residents experience mishaps: Implications for learning in context. Refereed invited presentation at the Organizational Learning and Knowledge Management Conference, Ivey School of Business, University of Western Ontario, London, Ontario, Canada.

Sutcliffe, K.M. 2000. Faulty perceptions and strong performance: Management by interpretation. Invited presentation. Stern School of Business, New York University, New York.

Sutcliffe, K.M. 2000. Executive team assessment of the business environment: Does accuracy matter. Invited presentation Hosmer Lunch series, University of Michigan Business School, Ann Arbor, MI.

Sutcliffe, K.M. 2000. Medical residents and medical mishaps: The re-embedding of practice. Invited presentation Darden Business School, Charlottesville, VA.

Confidential

Sutcliffe, K.M. 2000. Medical residents and medical mishaps: The re-embedding of practice. Adverse medical events: The resurrection of systems theory. Invited presentation ICOS, University of Michigan, Ann Arbor, MI.

Sutcliffe, K.M., Morris, I., Sitkin, S.B., Obstfeld, D., & Browning, L. 2000. Tailoring management tactics to situational requirements. Paper presented at the annual meetings of the Academy of Management, Toronto.

Bunderson, J.S. & Sutcliffe, K.M. 2000. Functional heterogeneity in management teams: Implications for process and performance. Paper presented at the annual meetings of the Academy of Management, Toronto.

Sutcliffe, K.M., & Weber, K. 2000. Environmental misperception and firm performance. Paper presented at the annual meetings of the Academy of Management, Toronto.

Sutcliffe, K.M. 2000. Organizational approaches to patient safety. Society for Academic Emergency Medicine, San Francisco.

Sutcliffe, K.M. 2000. Organizational approaches to patient safety. Paper presented to University of Florida Health Services Management Team and Department of Emergency Medicine, Jacksonville.

Sutcliffe, K.M. 2000. Learning and performance in management teams. Invited presentation Darden Business School, Charlottesville, VA.

Sutcliffe, K.M. 2000. Learning and performance in management teams. Paper presented to the School of Nursing, Department of Organization Systems, University of Michigan, Ann Arbor, MI.

Sutcliffe, K.M. 1999. A mindful infrastructure for organizational reliability. Paper presented at the annual meetings of the Academy of Management, Chicago, IL.

Weber, K. & Sutcliffe, K.M. 1999. Positive mindsets and exaggerated beliefs: Interpretive frames and firm performance. Paper presented at the annual meetings of the Academy of Management, Chicago, IL.

Sutcliffe, K.M., Vodosek, M., & Bunderson, J.S. 1999. Network interaction at the top: The emergence of top management team beliefs. Paper presented at the annual meetings of the Academy of Management, Chicago, IL.

Sutcliffe, K.M. 1999. Investigating a decision process in context. Paper presented to the Decision Consortium, University of Michigan, Ann Arbor, MI.

Sutcliffe, K.M. 1998. Learning and performance in top management teams: The role of norms, composition, and network interaction. Invited presentation Carnegie-Mellon University, Pittsburgh, PA.

Sutcliffe, K.M. & Weick, K.E. 1998. The reduction of medical error through systemic mindfulness. Paper presented at the Conference on Enhancing Patient Safety and Reducing Errors in Health Care. Rancho El Mirage, CA.

Sutcliffe, K.M. 1998. Accounting for change: Exploring executives' attributions in context. Paper presented to the Organizational Psychology Brown Bag, University of Michigan, Ann Arbor, MI.

Browning, L., Sitkin, S.B., & Sutcliffe, K.M. 1998. A structuration analysis of control and learning in TQM using organizations: The presence of feature and spirit in the reports of the use of procedures. Paper presented at the International Communication Association Annual Meeting, Jerusalem, Israel. Winner of the Top 3 best papers award.

Confidential

Sutcliffe, K.M. 1998. Managers in the Middle: The importance of managerial cognition for organizational outcomes. Discussion presented at the annual meetings of the Academy of Management, San Diego.

Sitkin, S., Sutcliffe, K.M., & Browning, L. 1998. Balancing seemingly antithetical process management approaches: Rediscovering formalization's role in effective innovation. Paper presented at the annual meetings of the Academy of Management, San Diego.

Sutcliffe, K.M. 1998. Critical perspectives on organizational learning. Invited presentation, Managerial and organizational cognition: Implications for entrepreneurship, decision making and knowledge management, Stern School of Business, New York University, New York, NY.

Sutcliffe, K.M. 1998. Organizing for high reliability: Creating an infrastructure for quality management. Invited presentation, April meeting of the LQIN, Brighton, MI.

Sutcliffe, K.M. 1997. Learning organizations and organizational learning: Separating the wheat from the chaff. Paper presented at the annual meetings of the Weed Science Society, Louisville, KY.

Sutcliffe, K.M. 1997. Decisions, decisions, decisions. Commentary presented at the annual meetings of the Academy of Management, Boston, MA.

Sutcliffe, K.M., Sitkin, S.B., Browning, L., & Obstfeld, D. 1997. Balance for competitive advantage: Control, learning, and quality management. Paper presented at the annual meetings of the Academy of Management, Boston, MA.

Sutcliffe, K.M. 1997. Organizing for high reliability: The organizational aspects of manufacturing. Invited presentation, University of Michigan, College of Engineering, Ann Arbor, MI.

Sutcliffe, K.M. 1997. Building capabilities: Learning processes in market unit teams. Invited presentation Duke University Fuqua School of Business, Durham, NC.

Sutcliffe, K.M. 1996. Developmental processes in management teams. Invited presentation University of Wisconsin School of Business, Madison, WI.

Sutcliffe, K.M. 1996. Managing change in a changing industry. Invited presentation at the second Precision Agriculture Conference, University of Minnesota, Minneapolis, MN (September).

Sutcliffe, K.M., & Sitkin, S.B. 1996. Balancing control and learning in total quality organizations. Invited presentation at the National Research Council Commission on Behavioral and Social Sciences and Education Workshop on Improving Theory and Research on Quality Enhancement in Organizations, Washington, DC.

Sutcliffe, K.M., & Bunderson, S.J. 1996. Competence learned: Developmental processes in organizational teams. Paper presented at the annual meetings of the Academy of Management, Cincinnati, OH.

Obstfeld, D., & Sutcliffe, K.M. 1996. Everyday reliability in traditional organizations: Learning from high reliability organizations. Paper presented at the annual meetings of the Academy of Management, Cincinnati, OH.

Sutcliffe, K.M. 1996. Rethinking the relationship between work history and selective perception. Invited presentation at the University of Utah, School of Business Administration, Salt Lake City, UT.

Sutcliffe, K.M. 1996. Initiating change in the agricultural industry. Invited presentation at Precision Agriculture Conference, University of Minnesota, Minneapolis, MN (February).

Confidential

Sitkin, S.B., Sutcliffe, K.M., & Browning, L.B. 1996. Distinguishing control from learning in Total Quality Management. Paper presented at the annual meetings of the NSF Design and Manufacturing Grantees Conference, Albuquerque, NM.

Sutcliffe, K.M. and Zaheer, A. 1995. Uncertainty in the transaction environment: An empirical test. Paper presented at the annual meetings of the Academy of Management, Vancouver, BC.

Sutcliffe, K.M. 1995. TQM as an organizing construct for the conduct of significant research. Paper presented in a symposium entitled "Interdisciplinary research as a tool for transforming work and organizations for the 21st Century: Lessons learned from TQM" at the annual meetings of the Academy of Management, Vancouver, B.C.

Bunderson, J.S. & Sutcliffe, K.M. 1995. Work history and selective perception: Fine-tuning what we know. Paper presented at the 1995 annual meetings of the Academy of Management, Vancouver, BC.

Sutcliffe, K.M. 1995. Rethinking the relationship between work history and selective perception. Invited paper presentation, Nanyang Technological University, Singapore.

Sutcliffe, K.M. 1995. Action taking and learning from action in complex environments. Paper presented at the annual international meeting of ORSA/TMS, Singapore.

Sutcliffe, K.M. 1994. Coping with environmental complexity: Surprise, sensemaking, and strategic learning. Paper presented at the annual national meeting of ORSA/TIMS, Detroit, MI.

Sutcliffe, K.M., Waller, M.J., & Huber, G.P. 1994. Accounting for change: Exploring the antecedents of causal attributions. Paper presented at the annual meetings of the Academy of Management, Dallas, TX.

McEvily, S., Sutcliffe, K.M., & Marcus, A. 1994. Explaining preferences for public policy: Strategic and contextual determinants. Paper presented at the annual meetings of the Academy of Management, Dallas, TX.

McNamara, G., & Sutcliffe, K.M. 1994. Justifying risk-rating decisions in commercial lending: The influence of routines, organization change, and uncertainty. Paper presented at the annual meetings of the Academy of Management, Dallas, TX.

McEvily, S., Sutcliffe, K.M. 1994. Explaining preferences for environmental regulation. Paper presented at the TIMS XXXII conference, Anchorage, AK.

Sutcliffe, K.M. Accurate perceptions in top management teams: Antecedents, consequences, and future research directions. Invited presentation, University of Calgary, Faculty of Management, November, 1993.

Sutcliffe, K.M. The role of managerial interpretations in influencing strategic adaptation. Paper presented at the 1993 meetings of the Strategic Management Society, Chicago, IL.

Sutcliffe, K.M. Perceptual paradox: The perils and promises of misperceiving the environment. Chair, symposium presentation at the 1993 annual meetings of the Academy of Management, Atlanta, GA.

Sutcliffe, K.M. What executives notice: Accurate perceptions in top management teams. Paper presented at the 1993 annual meetings of the Academy of Management, Atlanta, GA.

Sitkin, S. B., Sutcliffe, K. M., & Reed, G.L. 1992. Prescriptions for justice: Using social accounts to legitimate the exercise of professional control. Paper presented at the annual meeting of the International Association for Conflict Management in Minneapolis, MN.

Confidential

Huber, G.P., Sutcliffe, K.M., Miller, C.C., & Glick, W.H. 1991. Determinants of organizational changes: A comparison of their relative impact. Paper presented at the annual meetings of the Academy of Management, Miami Beach, Florida.

Sitkin, S. B., Barrios-Choplin, J. R., & Sutcliffe, K. M. 1990. Employee responses to acquisitions: The effect of perceived change, uncertainty, equivocality, and acquiring firm ethical values on employee stress. Paper presented at the annual meetings of the Academy of Management, San Francisco.

Huber, G. P., Sutcliffe, K. M., & Glick, W. H. 1989. Environmental determinism and strategic choice: Empirical analyses of their relationships and subcomponent relationships. Paper presented at the annual meetings of the Academy of Management, Washington, D.C.

Sitkin, S. B., & Sutcliffe, K. M. 1989. Dispensing legitimacy: Professional, managerial, and legal influences on pharmacist use of social accounts. Paper presented at the annual meetings of the Academy of Management, Washington, D.C.

Huber, G. P., Sutcliffe, K. M., & Glick, W. H. 1988. An empirical examination of strategic choice and environmental determinism as determinants of strategic organizational changes. Paper presented at the annual meetings of the Academy of Management, Anaheim, California.

Sitkin, S. B., Barrios-Choplin, J. R., & Sutcliffe, K. M. 1988. Interpreting communication media: Employee responses to a merger. Paper presented at the annual meetings of the Academy of Management, Anaheim, California.

Sutcliffe, K. M. 1987. Organizational justifications across the life cycle. Paper presented at the annual meetings of the Academy of Management, New Orleans, Louisiana.

Sitkin, S. B., Reed, L., & Sutcliffe, K. M. 1987. Organizational and legal justifications for disclosive and non-disclosive behavior: An empirical study of pharmacist use of social accounts. Paper presented at the annual meetings of the Academy of Management, New Orleans, Louisiana.

Sutcliffe, K.M. 1985. The movement from colonialism to community based care in rural Alaska. Paper presented at the 1985 Annual Conference of the American Public Health Association, Washington, D.C.

Sutcliffe, K. M., & Burrelle, R. K. 1985. The value of self-care programs for rural elderly. Paper presented at the 1985 Annual Conference of the National Council on Aging, San Francisco, California.

TEACHING

Undergraduate degree program courses:

- Behavioral Theory in Management (University of Michigan)
- Fundamentals of Management (University of Minnesota)

Graduate degree program courses:

- Power and Politics (MBA) (Johns Hopkins University)
- Leading Strategic Change (E/MBA) (Johns Hopkins University, University of Michigan)
- Human Behavior and Organizations (MBA day core course, Global MBA core course, MBA evening core course) (University of Michigan)
- Leading Change (EMBA core course, University of Michigan Ann Arbor & LA cohorts)
- Management and Organizations for Lawyers (University of Michigan Law School Elective)
- Management and Organizational Behavior (University of Michigan MBA core course)
- Mechanisms of Theory (University of Michigan PhD course)
- Multidisciplinary Action Project (University of Michigan MBA required course)
- The Management of Change (University of Minnesota MBA core course)

Confidential

Organizational Behavior and Managerial Analysis (University of Minnesota MBA elective)
 Sensemaking in Organizations (University of Minnesota Ph.D. elective)

Executive education

Armstrong Institute Patient Safety and Quality Leadership Academy
 Bloomberg Philanthropies City Data Alliance Inaugural Mayoral Class
 Kingdom of Saudi Arabia (KSA) – Healthcare Leadership Development (Johns Hopkins Carey Business School)
 Executive Certificate – Academy for Healthcare Leadership and Management (Johns Hopkins Carey Business School)
 High Reliability Leadership (Johns Hopkins Carey Business School)
 Intelligence Learning Network (University of Michigan)
 Bank of America Leadership Program (University of Michigan)
 HR Network (Vienna) (University of Michigan)
 Seminarium HR Program (Chile, Costa Rica, Panama) (University of Michigan)
 ATKearney MBA Essentials Program (University of Michigan)
 Management of Managers Program (University of Michigan)
 National Intelligence Service (Washington, DC) (University of Michigan)
 Strategic Quality Management Program (University of Michigan)

INSTITUTIONAL SERVICE

2020-present	Member of the JHU Tenure Advisory Committee (TAC)
2018-present	Member Carey School APT and Academic Board
2023-2024	Chair Carey MO Faculty Recruiting Committee
2023-2024	Member Carey Governance Committee
2023-2024	Member Carey PhD Program Exploration Committee
2023-2024	Chair Carey Business School M&O Faculty recruiting committee
2022-2023	Member doctoral dissertation committee for So Yeon Kang, JHU Bloomberg School of Public Health
2022-2023	Chair Carey Business School Carey Distinguished Professorship faculty recruiting committee
2021-2023	Member of the Carey Distinguished Professorship faculty recruiting committee
2022-2023	Chair doctoral dissertation committee Rebecca Ojo, JHU Bloomberg School of Public Health
2022	Chair Carey Business School Vice-Dean Search committee
2021-2022	Member of the Carey Special Committee of the PhD Program
2021-2022	Co-chair Carey Business School M&O Faculty recruiting committee
2020-2021	Member of the JHU University Pandemic Academic Advisory Committee (UPAAC)
2019	Chair Carey Business School M&O Faculty recruiting committee
2017-2019	Member doctoral dissertation committee Teddy DeWitt University of Michigan
2019	Member Carey School Dean Search Committee
2017-2019	Chair doctoral dissertation committee Alden Lai, JHU Bloomberg School of Public Health
2018	Chair Carey Business School Postdoctoral Fellow MO/Healthcare recruiting committee
2018	External doctoral dissertation examiner Vibeke Milch, Norwegian University of Science and Technology, Trondheim Norway
2018	External doctoral dissertation examiner Bettina Ravnborg Thude, University of Southern Denmark, Odense, Denmark
2017-2018	Chair Carey Business School Marketing search committee
2016-2017	Chair doctoral dissertation committee Lori Paine
2015-2016	External doctoral dissertation examiner Gunhild Saetren, Norwegian University of Science and Technology, Trondheim Norway
2013-2015	Member doctoral dissertation committee Kristin Alvarez

Confidential

2012-2015 Chair doctoral dissertation committee Matt Karlesky
 2012-2015 Chair doctoral dissertation committee Chris Meyers
 2013 Member doctoral dissertation committee Amanda Fore
 2013-2015 Member doctoral dissertation committee Lok-Sze Wong
 2013-2015 Member doctoral dissertation committee Kelly McMahon
 2013-2015 Member doctoral dissertation committee Elias Samuels
 2012-2014 Member doctoral dissertation committee Johan Chu
 2012-2014 Co-chair doctoral dissertation committee Laura Rees
 2013-2014 Member doctoral dissertation committee Heather Beasely
 2012-2013 Member University Search Committee for Executive Director of Safety and Security
 2012-2013 Chair ZLI Executive Director Recruiting Committee
 2010-2012 Co-chair doctoral dissertation committee Maria Farkas
 2010-2012 Member dissertation committee Na-Eun Cho
 2010-2012 Member dissertation committee Flannery Stevens
 2010-2011 Member dissertation committee Adam Cobb
 2010-2014 Member dissertation committee Viticia Thames
 2009-2012 Member dissertation committee Seneca Rosenberg
 2008-2012 Member dissertation committee Christine Neumerski
 2010-2011 Member dissertation committee Francesca Forzani
 2008-2011 Member dissertation committee Deleise Wilson
 2008-2010 Chair doctoral dissertation committee Michelle Barton
 2006-2009 Co-chair doctoral dissertation committee Dan Gruber
 2006-2009 Chair doctoral dissertation committee Marlys Christianson
 2006-2009 Member dissertation committee Olenka Kacperczyk
 2006-2007 Member doctoral dissertation committee Sean Delaney
 2006-2007 Undergraduate Honors Thesis Advisor for Melissa Kamin
 2006 External examiner for doctoral exam University of Calgary
 2005-2007 Member Ross School Executive Committee
 2005-2007 Member doctoral dissertation committee Brianna Barker Caza
 2005-2006 Member prelim/IERP committee Olenka Kacperczyk
 2005-2006 Member prelim/IERP committee Dan Gruber
 2005-2006 Member prelim/IERP committees Michelle Barton
 2003-2005 Chair doctoral studies committee UMBS
 2003-2005 M&O doctoral studies coordinator
 2004-2005 Undergraduate Honors Thesis Advisor for Elizabeth Campbell
 2004-2005 Member prelim/IERP committees Marlys Christianson
 2004-2007 Member doctoral dissertation committee Scott Sonenshein
 2004-2008 Member doctoral dissertation committee Ruth Blatt
 2004-2007 Member doctoral dissertation committee Aran Caza
 2004-2006 Member doctoral dissertation committee Melissa Wooten
 2003-2006 Member of the Domestic Corps Advisory Committee
 2003-2005 Member doctoral dissertation committee Dana Tschannen
 2003-2004 Member doctoral dissertation committee Jane Zhao
 2002-2004 Chair doctoral dissertation committee for Tim Vogus
 2001-2004 Member doctoral dissertation committee for Elizabeth McCance
 2002-2003 Member of prelim committee for Melissa Wooten
 2001-2003 Member doctoral dissertation committee for Klaus Weber
 2001-2003 Member doctoral dissertation committee for Ryan Quinn
 2001-2002 Member doctoral dissertation committee for Samina Karim
 2001-2002 Member of UMBS EE Advisory committee
 2001-2002 Chair, OBHRM Recruiting committee
 2000-2001 Member of UMBS research committee
 2000-2001 MBA OBHRM core course coordinator
 1997-2001 Member doctoral dissertation committee for David Obstfeld

1998-2001	Member doctoral dissertation committee for Valter Moreno
1999-2000	Member of doctoral dissertation committee for Thomas Sy
1999-2000	Member of doctoral dissertation committee for Darryl Wahlstrom
1999-2000	Member of prelim exam committee for Ryan Quinn
1998-1999	Member faculty recruiting committee
1998-2000	Member doctoral dissertation committee for Jin Nam Choi
1998-2002	Member doctoral dissertation committee for Randy VanWagoner
1998-2000	Member doctoral dissertation committee for Michael Metzger
1997-1998	MBA OBHRM core course coordinator
1997-1998	Member doctoral dissertation committee for Diane Norris
1995-1998	Member doctoral dissertation committee for Caroline Bartel
1996-1997	Member faculty recruiting committee
1995-1998	Member doctoral dissertation committee for Vince Linder
1995-1996	Member doctoral student recruitment committee
1994-1995	Member doctoral student recruitment committee
1994-1996	Member doctoral dissertation committee for Melinda Spencer
1994-1995	Member doctoral dissertation committee for Patricia Benson
1994-2003	Member doctoral dissertation committee for Sheherezade Taylor
1994-1996	Member doctoral dissertation committee for Sharon Manceor

HONORS, AWARDS AND RECOGNITION

2024	Named one of AACSB's 2024 Class of Influential Leaders
2024	Appointed Kenan Institute Distinguished Research Fellow for 2024
2021-present	Appointed by the National Academies of Science, Engineering and Medicine Transportation Research Board to a Committee on Emerging Trends in Aviation Safety.
2020	Elected Fellow of the International Academy of Quality and Safety in Health Care (IAQS)
2019	Reviewer, National Academy of Sciences, Engineering, and Medicine, Gulf Research Program, Safer Offshore Energy Systems Grants
2018	McCombs School of Business Distinguished PhD Alumnus Award
2018	Elected Fellow of the Academy of Management (AOM)
2016	Awarded Rockefeller Foundation Bellagio Residency Fellowship July-August
2015	Awarded the MOC Distinguished Scholar Award by the Managerial and Organizational Cognition Division of the Academy of Management.
2012-2015	Appointed by the National Academy of Sciences Institute of Medicine to a research panel charged with studying and providing recommendations related to workforce resilience to the Department of Homeland Security.
2012	Awarded grant by the National Institute of Health to conduct a study to understand variation in failure to rescue in the elderly (co-primary investigator Dr. John Birkmeyer et al, University of Michigan, \$999,337)
2010-2014	Awarded Robert Wood Johnson Foundation Investigator Award (co-primary investigator Dr. Robert Wears, University of Florida, \$335,000)
2006	Awarded Researcher of the Year Award, Ross School of Business, University of Michigan
2006	Awarded Ross School of Business Research Grant (\$5000)
2005	Faculty OMT/MOC Doctoral Consortium, Academy of Management Meetings
2005	Awarded grants by the Ross School of Business, and the University of Michigan Office of the Vice President for Research for a conference on "resilience" (\$5000, \$10000).
2004	Awarded grant by the University of Michigan ICOS for a conference on "resilience" (\$5000).

- 2003 Awarded grant by the University of Michigan Office of the Vice President for research to conduct a narrative study of “thriving” (co-investigator Dr. Jane Dutton, Dr. Gretchen Spreitzer, University of Michigan, \$7800).
- 2003 Top ten paper (co-authored with Tim Vogus) Strategic Management Society
- 2003 Top three paper (co-authored with Karl Weick) California Management Review
- 2001 Awarded grant by the Agency for Healthcare Research and Quality to conduct a working conference to develop a multidisciplinary research direction for studying errors in HCOs (co-primary investigators Dr. Robert Wears, University of Florida Medical School and Dr. Saul Weingart, Harvard University, \$50,000)
- 2001 Awarded grant by the National Patient Safety Foundation for a two-year multi-method study of errors in emergency departments (co-primary investigator Dr. Robert Wears, University of Florida Medical School, \$110,000)
- 2000 Best paper award by the International Communication Association, Seattle, Washington
- 2000 Awarded grant by the University of Michigan Office of the Vice President for research to investigate the organizational factors associated with medical mishaps (co-investigator Dr. Marilyn Rosenthal, University of Michigan, \$15,000).
- 1999 Best paper award by the International Communication Association, San Francisco, CA.
- 1998 Best paper award by the International Communication Association, Jerusalem, Israel.
- 1996-1998 GE Lighting Faculty Fellowship awarded by the Tauber Manufacturing Institute, University of Michigan
- 1996-1997 NBD Bancorp Award for Junior Faculty Achievement, University of Michigan Business School, 1996.
- 1995 Best paper award by the Management and Organizational Cognition Interest Group of the Academy of Management.
- 1995 Awarded grant by the Center for International Business Education, University of Michigan to conduct a comparative research project into the joint information processing behaviors of firms in Singapore (\$3,000).
- 1995-1998 Awarded National Science Foundation research grant for three-year study of quality in American firms (co-primary investigator with Sim Sitkin, Duke University, \$420,000).
- 1993-1994 Awarded University of Minnesota Graduate School research grant (\$14,000).
- 1992-1993 Awarded University of Minnesota Graduate School research grant (\$10,000).
- 1992-1993 Bush Faculty Development Program on Excellence and Diversity in Teaching, University of Minnesota.
- 1992-1993 Awarded \$20000 research grant by the McKnight Foundation (with A. Marcus) to study the Minnesota energy efficiency and renewable fuels industry.
- 1992 Academy of Management OB/OT/OD new faculty consortium.

PROFESSIONAL SERVICE/MEMBERSHIPS

Editorial Review Board Member: *Academy of Management Discoveries*, *Academy of Management Perspectives*, *International Public Management Journal*, *Academy of Management Journal* (1999-2004), *Organization Science* (1999-2013), *Organization Studies* (Senior Editor- 2003-2009), *Academy of Management Annals Advisory Board* (2013-present), *Journal of Management Studies* Special Issue Commemorating the 50th Anniversary of the Publication of Karl E. Weick’s *The Social Psychology of Organizing* (2018-2020), Special Issue on *Academy of Management Review* Special Issue on the New Normal (2020-present), Special Issue on *Journal of Management Studies* Special Issue on Extreme Contexts (2021-present)

Ad Hoc Reviewer: *Academy of Management Discoveries*, *Academy of Management Review*, *Academy of Management Journal*, *Administrative Science Quarterly*, *BMJ Leader*, *BMJ Quality and Safety in Healthcare*, *British Journal of Management*, *Human Relations*, *Journal of Management Studies*, *Management Science*, *Medical Care*, *Organization Science*, *Organization Studies*, *Safety Science*, *Strategic Management Journal*

*Confidential***Academy of Management:**

- Past Chair of the Managerial and Organizational Cognition Division of the Academy of Management (1998-2002)
- Ad Hoc Program Reviewer (e.g., MOC, OB, OMT, and BPS)
- Best Paper Award Reviewer (e.g., AOM Fellows RRIM award, AMJ, Annals) (ongoing)
- AOM meetings Research in the Rough (for MOC and HCM) (ongoing)

Professional Memberships

- Academy of Management (AOM)
- European Group for Organization Studies (EGOS)
- Institute for Operations Research and Management Science (INFORMS)
- Strategic Management Society

OTHER EMPLOYMENT/CONSULTING

- Director Health and Social Services (Aleutian/ Pribilof Islands Association, Anchorage, Alaska), 1983-1986; Program Consultant (State of Alaska, Dept. of Health and Social Services, Juneau, Alaska), 1981-1983; Instructor, Community Health Care (University of Washington, Seattle, Washington), 1980; Public Health Nurse Practitioner (Iliuliuk Family and Health Services, Unalaska, Alaska), 1978-1979.
- Various consulting engagements (some examples): Previous consulting with the Analysis Group, Fire Department of New York, Georgia Pacific, Goldman Sachs, Marathon Oil Company, Secretary of the Navy, Navy Surgeon General, Air Force Surgeon General, Department of Interior, United States Forest Service, Cincinnati Children's Hospital and Medical Center, ThyssenKrupp, SABIC, ProRail, General Electric, Hewlett Packard, Target, Motorola, Xerox, Applied Materials, the State of Alaska, and the US Bureau of Mines.

*Confidential***Appendix B****Kathleen M. Sutcliffe
List of Expert Testimony**

- **Sandoval v. American Water Heater Company, et al.**
Superior Court of the State of California for the County of Los Angeles

- **In Re: Vale S.A. Securities Litigation**
United States District Court, Eastern District of New York

Confidential

Appendix C Documents Considered

Materials Produced in the J&J Baby Powder/Talc Product Litigation Matters

Initial Tranche of Documents

- 1955.02.22 - DX7000
- 1957.10.15 - DX8381
- 1958.05.23 - DX8383
- 1958.07.18 - DX8382
- 1959.02.17 - JNJAZ55_000001114
- 1959.07.31 - DX8384
- 1959.08.31 - DX8385
- 1959.09.15 - DX8386
- 1959.12.31 - DX8387
- 1960.03.08 - DX8388
- 1960.04.12 - DX8389
- 1961.06.06 - JNJALC000129140
- 1962 - DX7988
- 1962 - J of SC Med. Assoc
- 1962.01.04 - New England J of Medicine
- 1963 - JNJ 000252260
- 1963.05.27 - JNJ 000087425
- 1964.02.21 - JNJ 000265536
- 1964.11.03 - DX8201
- 1966.04.07 - JNJALC000301073
- 1966.06.17 - JNJNL61_000009898
- 1966.07.13 - DX7731
- 1966.07.13 - DX8205
- 1966.07.14 - DX8202
- 1967.01.30 - JNJAZ55_000011185
- 1967.05.23 - JNJALC000088494
- 1967.11.01 - JNJAZ55_000012423
- 1968.01.24 - JNJ 000087825
- 1968.01.24 - JNJAZ55_000001169
- 1968.01.25 - DX9476
- 1969.04.09 - DX7724
- 1969.04.10 - JNJ 000089440
- 1969.04.15 - JNJ 000087991
- 1969.04.24 - JNJ 000089431
- 1970.07.14 - JNJALC000168264
- 1970.08.14 - JNJALC000291693
- 1970.08.24 - JNJALC000070222
- 1970.12.04 - JNJAZ55_000015127
(Excerpt)
- 1971 - DX8197
- 1971.01.23 - JNJMX68_000005969
- 1971.03.00 - DX9954
- 1971.03.19 - CSMRI
- 1971.04.01 - CSMRI
- 1971.04.14 - [L-0414] No Bates
- 1971.04.23 - JNJALC000290177
- 1971.04.30 - DX8390
- 1971.04.30 - JNJAZ55_000005725
- 1971.05.25 - JNJALC000290181
- 1971.05.25 - JNJALC000290184
- 1971.06.19 - JNJMX68_000015772
- 1971.06.29 - JNJMX68_000015774
- 1971.06.30 - DX8369
- 1971.07.07 - JNJAZ55_000006088
- 1971.07.08 - DX7011
- 1971.07.09 - JNJAZ55_000005743
- 1971.07.09 - JNJMX68_000008782
- 1971.07.20 - DX8204
- 1971.07.21 - DX8203
- 1971.07.30 - JNJ 000233053
- 1971.07.30 - JNJNL61_000008624
- 1971.08.06 - DX7014
- 1971.08.06 - JNJMX68_000007007
- 1971.08.09 - JNJ 000232501
- 1971.08.09 - JNJNL61_000022019
- 1971.08.10 - DX7017
- 1971.08.13 - JNJ 000373313

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- 1971.08.13 - JNJAZ55_000004904
- 1971.08.19 - DX7019
- 1971.08.31 - JNJ 000260770
- 1971.09.03 - DX7022
- 1971.09.03 - JNJAZ55_000008893
- 1971.09.29 - No Bates (FOIA)
- 1971.10.11 - JNJAZ55_000003635
- 1971.10.14 - JNJ TALC000589478
- 1971.11.10 - JNJ 000260873
- 1971.11.10 - JNJAZ55_000005253
- 1971.11.18 - JNJ 000232511
- 1971.12.10 - JNJ 000254366
- 1971.12.22 - JNJ 000233499
- 1972 - JOJO-MA2546-01282
- 1972.01.00 - JNJMX68_000007031
- 1972.01.27 - DX7723
- 1972.02.03 - DX7116
- 1972.03.15 - DX8409
- 1972.05.01 - JNJ 000346723
- 1972.05.22 - DX8198
- 1972.06.17 - DX7032
- 1972.06.17 - JNJNL61_000001123
- 1972.06.20 - JNJMX68_000004624
- 1972.06.23 - JNJNL61_000016275
- 1972.08.11 - DX8371
- 1972.08.12 - JNJ 000244639
- 1972.08.14 - JNJAZ55_000003648
- 1972.08.24 - JNJ 000270070
- 1972.08.30 - DX8068
- 1972.08.31 - DX8025
- 1972.09.08 - DX7038 (Excerpt)
- 1972.09.08 - DX8817
- 1972.09.25 - DX8708
- 1972.09.26 - DX7041
- 1972.09.26 - JNJ 000232996
- 1972.09.27 - DX7043
- 1972.09.28 - DX7044
- 1972.09.28 - DX8015
- 1972.10 - DX7046
- 1972.10.08 - DX8407
- 1972.10.09 - DX8705
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- 1972.10.18 - 29 CFR 1910
- 1972.10.27 - DX8057
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- 1972.11.08 - DX7051
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- 1972.11.29 - JOJO-MA2546-01365
- 1972.12.13 - DX7054
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- 1973.01.12 - JNJ 000261816
- 1973.01.15 - JNJNL61_000007240
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- 1973.01.25 - DX8257
- 1973.01.29 - JNJAZ55_000004172
- 1973.02.08 - JNJNL61_000016536
- 1973.02.20 - JNJNL61_000064937
- 1973.02.26 - 57-0163
- 1973.03.06 - DX7057
- 1973.03.08 - JNJNL61_000063476
- 1973.03.12 - DX7058
- 1973.03.14 - DX7732
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- 1973.03.14 - JNJAZ55_000005041
- 1973.03.30 - JNJ 000232297
- 1973.03.30 - JNJAZ55_000014444
- 1973.04.13 - JNJ 000232985
- 1973.04.19 - JNJ 000245155
- 1973.04.20 - DX8265
- 1973.04.24 - JNJNL61_000008749
- 1973.04.26 - JNJ 000294872

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- 1973.04.27 - JNJ 000273729
- 1973.05.08 - JNJ 000223814
- 1973.05.08 - JNJAZ55_000008888
- 1973.05.16 - JNJ 000232679
- 1973.05.22 - JNJAZ55_000001892
- 1973.06.04 - DX8217
- 1973.06.04 - JNJ 000231419
- 1973.06.06 - JNJAZ55_000005081
- 1973.06.06 - JNJALC000168016
- 1973.06.08 - DX8726
- 1973.06.22 - DX8154
- 1973.08.08 - JNJAZ55_000006196
- 1973.08.20 - FDA Memo
- 1973.09.06 - DX8188
- 1973.09.19 - DX8218
- 1973.09.20 - DX7070
- 1973.09.28 - JNJ 000086280
- 1973.10.01 - DX7073
- 1973.10.05 - DX7075
- 1973.10.22 - JNJ 000086234
- 1973.10.23 - JNJAZ55_000006212
- 1973.10.23 - JNJNL61_000008742
- 1973.10.26 - JNJAZ55_000002042
- 1973.11.09 - DX7078
- 1973.11.19 - JNJALC000359850
- 1973.11.26 - JNJMX68_000007044
- 1973.12.07 - No Bates
- 1973.12.11 - DX7079
- 1973.12.12 - DX8256
- 1973.12.13 - JNJALC000376583
- 1973.12.20 - DX7080
- 1973.12.27 - CSMRI Report
- 1974 - EMSA Meeting
- 1974 - Rowlands - Investigation into talc powders imported into the United (Excerpt)
- 1974.01.18 - JNJ 000488208
- 1974.02.07 - DX8246
- 1974.02.08 - DX8247
- 1974.02.10 - JNJNL61_000006431
- 1974.02.11 - JNJNL61_000008111
- 1974.02.14 - DX8740
- 1974.03.00 - DX7083
- 1974.03.00 - JNJ 000231693
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- 1974.03.13 - JNJAZ55_000005914
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- 1974.04.24 - DX8410
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- 1974.05.14 - DX7089
- 1974.05.14 - JNJAZ55_000009380
- 1974.05.16 - DX7090
- 1974.05.29 - No Bates
- 1974.06.20 - JNJMX68_000005051
- 1974.07.08 - DX7095
- 1974.07.08 - JNJALC000287009
- 1974.08.08 - DX8111
- 1974.08.23 - JNJ 000086638
- 1974.09.24 - DX7836
- 1974.10.10 - DX8814
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- 1974.10.30 - DX8374
- 1974.12.17 - JNJ 000267138
- 1975.01 - DX8264
- 1975.01.14 - DX7100
- 1975.02.13 - JNJAZ55_000013775
- 1975.02.18 - JNJALC000168174
- 1975.02.24 - CAMC-Sabatelli-000677
- 1975.02.28 - JNJ 000264747
- 1975.03.31 - JNJAZ55_000009265
- 1975.04.10 - DX8065
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- 1975.05.29 - JNJAZ55_000010706
- 1975.06.11 - JNJ 000687275
- 1975.07.00 - DX8250
- 1975.07.01 - DX8375
- 1975.07.09 - DX8249 (Excerpt)
- 1975.07.14 - JNJAZ55_000010568
- 1975.07.18 - JNJ 000221705
- 1975.07.23 - DX8535
- 1975.08.00 - DX8251
- 1975.09.22 - DX9471
- 1975.09.29 - JNJ 000061649
- 1975.10.20 - DX8211
- 1975.11.05 - DX8376
- 1975.11.19 - DX7112
- 1975.11.21 - DX8240
- 1976 - DX8096
- 1976 - DX8537
- 1976 - DX9383
- 1976.01.07 - DX7113
- 1976.01.08 - DX7114
- 1976.02.27 - DX8248
- 1976.03.02 - DX8267
- 1976.03.08 - DX7996
- 1976.03.10 - DX8402
- 1976.03.12 - DX7577
- 1976.03.15 - JNJNL61_000021692
- 1976.03.22 - DX8803
- 1976.03.22 - JNJMX68_000018722
- 1976.03.23 - DX7119
- 1976.03.26 - JNJ 000277175
- 1976.03.26 - JNJ 000304381
- 1976.03.31 - JNJ 000252948
- 1976.03.31 - JNJTALC000169805
- 1976.03.31 - WCD000162
- 1976.04.26 - DX7122
- 1976.05.10 - DX8818
- 1976.05.20 - BASF_EMTAL000002211
- 1976.05.24 - DX7694
- 1976.06.04 - DX7125
- 1976.06.25 - DX8022
- 1976.08.31 - DX8536
- 1976.09.22 - JNJNL61_000034842
- 1976.10.07 - DX7131
- 1976.10.18 - Memo from Estrin to CTFA
- 1976.11.00 - What You Want to Know about JBP
- 1976.11.24 - JNJNL61_000017453
- 1976.12.30 - JNJ 000252257
- 1977 - DX8538
- 1977 - DX9053
- 1977.01.12 - DX7721
- 1977.01.20 - DX8207
- 1977.02.01 - JNJNL61_000020392
- 1977.02.22 - DX8209
- 1977.02.25 - DX8196
- 1977.03.21 - DX7982
- 1977.03.31 - JNJ 000250539
- 1977.04.01 - JNJ 000061131
- 1977.04.05 - DX8377
- 1977.04.21 - DX8206
- 1977.04.29 - DX7141
- 1977.05.00 - DX7477
- 1977.05.17 - CTFA Meeting Minutes re round robin results
- 1977.06.28 - DX7143
- 1977.07.18 - JNJ 000245678
- 1977.08.10 - BASF_EMTAL000002244
- 1977.08.12 - DX7144
- 1977.08.26 - JNJNL61_000067783
- 1977.10.10 - DX8200
- 1977.11.03 - DX8215
- 1977.11.03 - JNJAZ55_000009126
- 1977.11.09 - DX8021
- 1977.11.22 - JNJNL61_000020439
- 1977.12.06 - JNJNL61_000020414

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- 1977.12.27 - JNJ TALC000168745
- 1978.01.05 - DX8214
- 1978.02.08 - JNJ 000325951
- 1978.02.09 - JNJ 000295352
- 1978.02.23 - DX7147
- 1978.03.01 - DX8208
- 1978.03.02 - JNJ 000244013
- 1978.03.20 - DX8413
- 1978.08.23 - DX8231
- 1978.12.08 - DX8378
- 1979 - DX8079
- 1979 - DX8539
- 1979 - DX9010
- 1979 - DX9052
- 1979 - DX9382
- 1979 - DX9385
- 1979.01.11 - DX9199
- 1979.02.09 - J&J EX. 164
- 1979.12.20 - JNJ AZ55_000000024
- 1979-1980 - DX8540
- 1980 - DX9267
- 1980.09.08 - DX7164
- 1980.09.29 - DX7166
- 1980.11.06 - DX7165
- 1981 - DX8541
- 1982.01.15 - JNJ 000085114
- 1982.03.12 - JNJ 000085109
- 1982.08.12 - JNJ 000029640
- 1982.08.24 - [IC-62]
- 1983 - [P-626] Gambino ROGs
- 1983 - DX8543
- 1983.06.03 - DX8030
- 1983.06.28 - DX8019
- 1983.06.28 - DX8031
- 1983.08.16 - DX8032
- 1983.09.29 - DX7183
- 1983.10.10 - DX7184
- 1983.11.30 - DX8033
- 1984 - DX9628
- 1984.02.24 - JNJ 000061164
- 1984.03.28 - DX7188
- 1984.04.25 - DX7191
- 1984.05.15 - CAMC-Herford-000119
- 1984.10.09 - DX7984
- 1984.10.23 - JNJ TALC000128300
- 1984.10.28 - DX7598
- 1984.11.02 - JNJ 000063266
- 1984.12.11 - DX7983
- 1985 - DX10060
- 1985 - DX8545
- 1985.06.06 - DX7201
- 1985.07.11 - DX7202
- 1985.08.02 - JNJ MX68_000013019
- 1985.08.22 - JNJ 000063206
- 1985.10.08 - JNJ NL61_0000424443
- 1985.11.18 - JNJ 000086587
- 1985.12.00 - DX8308
- 1986 - JNJ TALC000216929
- 1986.01.00 - JNJ 000000523
- 1986.01.17 - DX7206
- 1986.04.07 - DX7209
- 1986.04.29 - DX7210
- 1986.07.11 - DX7214 (Excerpt)
- 1986.09.08 - JNJ 000065616
- 1987.03.11 - McCrone ltr to JJ re analyses of talc by TEM_D-8169
- 1987.05.21 - DX7216
- 1987.07.20 - DX8712
- 1987.07.23 - [Sheridan Ex 3]
- 1987.09.29 - DX8720
- 1987.11.17 - JNJ TALC000215432
- 1988 - JNJ 000043779
- 1988 - Lamm and Starr
- 1988.03.14 - JNJ 000062175
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- 1988.10.13 - IMERYS 137704
- 1988.10.19 - DX8714
- 1988.12.29 - ITA-Sabatelli-000820
- 1989.01.13 - DX8045
- 1989.12.18 - DX8258
- 1990 - DX9666
- 1990 - DX9744
- 1990 - DX9955
- 1990.11.02 - DX7621
- 1990.11.26 - DX7235
- 1991 - JNJNL61_000014432
- 1991 - DX9035
- 1991 - IMERYS 211157
- 1991 - IMERYS 416192
- 1991.02.15 - DX8017
- 1991.02.21 - DX8004
- 1991.03.00 - IMERY 117589
- 1991.05.05 - DX7253
- 1991.06.07 - DX8122
- 1991.12.19 - JNJ 000312709
- 1991-1992 - AB-CYP-41-0001513
- 1991-1992 - McCrone reports to Cyprus Windsor
- 1992 - IMERYS 211157
- 1992 - Roggli
- 1992.01.13 - ITA-Guild-000839
- 1992.01.21 - DX8069
- 1992.01.21 - DX8723
- 1992.01.21 - DX8728
- 1992.03.25 - IMERYS219720
- 1992.06.08 - DX9335
- 1992.07.17 - JNJ 000021035
- 1992.08.05 - JNJ 000021093
- 1993.07.21 - JNJ 000011704
- 1993.11.23 - JNJ 000240739
- 1994.01.10 - DX8411
- 1994.01.11 - DX8199
- 1994.01.20 - JNJTALC000224226
- 1994.03.00 - JNJ 000015750
- 1994.05.02 - DX7381
- 1994.11.10 - JNJ 000016645
- 1995.08.21 - DX8393
- 1995.09.20 - JNJ 000035886
- 1995.10.13 - JNJ 000063951
- 1996 - DX10035
- 1996.01.29 - JNJ 000240529
- 1996.04.17 - IMERYS-A0011817
- 1996.06 - DX7409
- 1996.12.00 - JNJNL61_000013947
- 1996.12.05 - [IC-233]
- 1997 - DX9770
- 1997.09.17 - JNJ 000024462
- 1997.10.16 - JNJNL61_000058812
- 1997.10.20 - JNJ 000024495
- 1997.11.17 - DX7414
- 1998.04.23 - DX8380
- 1999.12.15 - IMERYS 213431
- 1999.12.15 - IMERYS 475679
- 2000 - Ahn Lee Kim Article re Tremolite to Talc Reaction in Ktalc
- 2000.01.25 - IMERYS 022644
- 2000.08.07 - IMERYS109346
- 2000.10.13 - LUZ023843
- 2000.10.13 - IMERYS 023842
- 2000.11.27 - JNJ 000238358
- 2000.11.29 - IMERYS100151
- 2000.11.30 - IMERYS 303842
- 2000.12.20 - IMERYS 239883
- 2001 - DX8291 (Excerpt)
- 2001 - DX9002 (Excerpt)
- 2001 - Ghio, Roggli
- 2001.01.04 - IMERYS 024289
- 2001.01.21 - IMERYS 467736
- 2001.01.31 - IMERYS 024364
- 2001.02.08 - IMERYS 209913
- 2001.03.17 - DX8259

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- 2001.05.17 - DX8701
- 2001.06.07 - J&J EX. 224
- 2001.10.29 - IMERYYS 239725
- 2002 - IMERYYS 021920
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- 2002.04.04 - IMERYYS 446794
- 2002.05.23 - IMERYYS 422289
- 2002.08.18 - Luzenac Argonaut Mine
VT - drilling outline - Downey Ex. 26
(MDL)
- 2003 - DX9074
- 2003.06.30 - JNJ 000389261
- 2003.09.30 - JNJ 000375304
- 2004 - Bowker - AVO website (2004)
- 2004 - Bowker Book Acknowledgment
- 2004 - Fatal Deception Excerpt 2
- 2004 - Fatal Deception Excerpt
- 2004.01.05 - JNJ 000375383
- 2004.02.23 - DX7418
- 2004.02.25 - DX8213
- 2004.02.26 - DX8288
- 2004.02.26 - DX8290
- 2004.02.27 - DX7728
- 2004.03.03 - DX7727
- 2004.03.09 - DX8076
- 2004.03.11 - ITA-Sabatelli-001630
- 2004.03.22 - IMERYYS 299277
- 2004.04.00 - JNJ 000124234
- 2005.02.01 - DX8216
- 2005.08.24 - JNJNL61_000101061
- 2006 - DX9265
- 2006 - JBP Presentation re identifying
benefits
- 2006.10.16 - JNJTALC000461499
- 2007 - DX9120
- 2007 - DX9952
- 2007.04.10 - IMERYYS 32241
- 2007.07.01 - DX9587
- 2007.10.02 - IMERYYS 493544-C
- 2007.10.22 - IMERYYS 441780
- 2008 - DX9306
- 2008 - DX9953
- 2008 - RTM Slide re no safe level
- 2008 - RTM TEM samples per year
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- 2008.01.03 - JNJTALC000852790
- 2008.01.31 - IMERYYS 442002
- 2008.04.18 - JNJ 000457161
- 2008.05.19 - DX8824
- 2009 - Egilman - Fiber types, Asb.
potency, & envir. causation
- 2009 - JNJTALC000355057
- 2009.08.04 - Rio Tinto Audit
- 2010 - DX9178 (Excerpt)
- 2010 - DX9777
- 2010.02.26 - JNJ 000133381
- 2010.03.29 - DX7435
- 2010.07.27 - DX7437
- 2010.11.29 - DX7438
- 2011 - DX9315 (Excerpt)
- 2011 - DX9428
- 2011 - DX9951
- 2011.03.02 - IMERYYS 245772
- 2011.04.00 - JNJ 000133309
- 2011.04.08 - DX7439
- 2011.04.25 - IMERYYS 027062
- 2011.04.26 - DX8210
- 2011.05.11 - DX7440
- 2011.05.13 - IMERYYS 308446
- 2011.05.24 - JNJTC_000002396
- 2011.06.02 - DX7985
- 2011.07.05 - DX8722
- 2011.07.20 - DX7441
- 2011.07.22 - DX7442
- 2011.08.19 - JNJNL61_000108827
- 2011.09.20 - JNJTALC0000399597
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- 2011.12.05 - IMERYYS 147942
- 2012.01.12 - DX7444
- 2012.03.28 - DX7445
- 2012.06.14 - DX8801
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 - October 2019: volumes PHA_GLOBAL_001, TALC_GLOBAL_001, TALC_GLOBAL_001_SS, TALC_GLOBAL_002, TALC_GLOBAL_002_SS, TALC_GLOBAL_003, TALC_GLOBAL_003_SS, and TALC_PROD_183 - TALC_PROD_207
 - June 2021: volumes TALC_PROD_208 - TALC_PROD_383 (J&J Defendants' production from the December 2019 supplementation to date)
- Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Responses to Plaintiff's LAOSD Standard Interrogatories, *Maricela Gutierrez v. Johnson and Johnson et al.*, Case No. 19STCV02585, Superior Court of the State of California for the County of Los Angeles, September 18, 2019, and the accompanying "Topics" spreadsheet.

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Statements from J&J Employees, including Deposition Testimony, Trial Testimony, and Primary Interviews

- Declaration of Dr. John Hopkins and corresponding exhibits, June 4, 2020.
- Deposition of Alice M Blount, Ph.D., *Gail Lucille Ingham and Robert Ingham, et al., v. Johnson & Johnson, et al.*, Case No. 1522-CC10417-01, April 13, 2018.
- Deposition of Christopher Picariello, *Teresa Elizabeth Leavitt and Deal J. McElroy v. Johnson & Johnson, et al.*, Case No. RGI 7882401, January 11, 2019.
- Deposition of Joan Casavieri, *Frank Hall v. Johnson & Johnson, et al.*, Civil Action No. 3:18-cv-01833 FLW-TJB, February 15, 2022.
- Deposition of Joanne Waldstreicher, M.D., and corresponding Exhibit 1, *Gail Lucille Ingham and Robert Ingham, et al., v. Johnson & Johnson, et al.*, Case No. 1522-CC10417, April 19, 2017.
- Deposition of Steven Mann, Volume I, *Mary Pulido and Victor Pulido, Jr. v. Johnson & Johnson, et al.*, Docket No. MID-L-4927-18AS, and *Sandra R. Weathers and Brian L. Weathers, v. Johnson & Johnson, et al.*, Docket No. MID-L-0549-20AS, February 15, 2021.
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Appendix D

Routine Testing of Johnson & Johnson's U.S. Cosmetic Talc Supply

This appendix provides a brief summary and examples of testing results that I have reviewed.¹ These test results are from the routine testing of J&J's U.S. cosmetic talc supply. A comprehensive summary of this testing can be found in **Figure 3**.

¹ Testing methods have limits of detection, which are “the smallest concentration/amount of the component of interest that can be determined by a single measurement with a stated level of confidence.” *See, e.g.*, “TEM Validation Process Guidelines,” *United States Environmental Protection Agency*, October 2016, available at <https://semspub.epa.gov/work/HQ/196840.pdf>. In other words, the limit of detection is the smallest amount of the component of interest that can be confidently distinguished from its absence or environmental/background contamination. *See, e.g.*, 2010 - DX9777 (“Specifically, a measurement is reported as being ‘below the [detection limit]’ if the measured level is not statistically different than the background level... The [detection limit], therefore, is a parameter in the statistical decision that determines whether the concentration of a substance in a sample is consistent with the background level, which may be zero, or is greater than the background level.”). Importantly, limits of detection do not indicate a test method *cannot* detect a component of interest. Even the most sensitive and reproducible test methods have limits of detection. *See, e.g.*, 1977.04.29 – DX7141 at 2 (TM7024 Specification) (“This method is capable of detecting a single fiber in the entire TEM field, a negligible level in terms of weight percentage. TEM/SAED is an ideal technique when the asbestos fiber size is $\leq 0.2 \mu\text{m}$.”), 1990 - DX9666 at 10 (Kremer and Millette’s “A Standard TEM Procedure for Identification and Quantitation of Asbestiform Minerals in Talc”) (“This method can detect a single fiber as small as 1 micrometer (μm) long by 0.075 (μm) wide in the entire TEM field, which results in a theoretical detection limit of 10-5 weight percent.”).

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Tester:	The McCrone Group
Test Material/Production Stage:	Ground Talc Ore
Testing Frequency/Date Range:	Weekly/Bi-weekly/Tri-weekly/Monthly, 1974 - 1996
Test Results Reviewed:	241 samples
Results:	No asbestos minerals were detected in any results reviewed.
Example Test Result Reference:	WTALC00002695
Example Test Result:	



RNM ✓
 walter c. mcrone associates, inc. *R-CCJF-R*
 CONSULTING: ULTRAMICROANALYSIS • MICROSCOPY • SMALL PARTICLE PROBLEMS • SOLID-STATE CHEMISTRY

31 March 1983

Dr. Harold G. Hills
 Windsor Minerals, Inc.
 P. O. Box 680
 Windsor, Vermont 05089

Dear Dr. Hills:

I have completed my asbestos analysis of thirty-three (33) talc samples submitted under your P.O. #303.

The samples were examined with the transmission electron microscope equipped for electron diffraction. No asbestos minerals were detected in any of the samples. The limit of detection of the method is approximately 0.1% by weight of asbestos. The samples are listed on the enclosed sheet.

Thank you for consulting McCrone Associates, and if you have any questions, please contact me.

Sincerely,

Richard M. Ellis, Jr.
 Richard M. Ellis, Jr.
 Research Microscopist

*Confidential***List of Test Results Reviewed:**

IMERYS 213444	JNJ 000280848	JNJTALC000071251
IMERYS 213445	JNJ 000280849	JNJTALC000071252
IMERYS 213450	JNJ 000280850	JNJTALC000071255
IMERYS 213451	JNJ 000280852	JNJTALC000071256
IMERYS-MDL-AB 0007557	JNJ 000280853	JNJTALC000071257
IMERYS-MDL-AB 0007558	JNJ 000280854	JNJTALC000071258
IMERYS-MDL-AB 0007559	JNJ 000280886	JNJTALC000071259
IMERYS-MDL-AB 0007561	JNJ 000280887	JNJTALC000071260
IMERYS-MDL-AB 0007564	JNJ 000280888	JNJTALC000071261
IMERYS-MDL-AB 0007565	JNJ 000280889	JNJTALC000071262
IMERYS-MDL-AB 0007566	JNJ 000280890	JNJTALC000071263
IMERYS-MDL-AB 0007567	JNJ 000280891	JNJTALC000071264
IMERYS-MDL-AB 0007568	JNJ 000280892	JNJTALC000071265
JNJ 000063281	JNJ 000280893	JNJTALC000071266
JNJ 000063284	JNJ 000280895	JNJTALC000071267
JNJ 000064190	JNJ 000280896	JNJTALC000071268
JNJ 000280774	JNJ 000280897	JNJTALC000071269
JNJ 000280775	JNJ 000280898	JNJTALC000071270
JNJ 000280777	JNJ 000280900	JNJTALC000071271
JNJ 000280778	JNJ 000280902	JNJTALC000071272
JNJ 000280782	JNJ 000291467	JNJTALC000298680
JNJ 000280783	JNJ 000291602	JNJTALC000387085
JNJ 000280785	JNJ 000291633	JNJTALC000387116
JNJ 000280786	JNJ 000291787	JNJTALC000387140
JNJ 000280788	JNJ 000292058	JNJTALC000387143
JNJ 000280790	JNJ 000292059	JNJTALC000387182
JNJ 000280793	JNJ 000292062	JNJTALC000387211
JNJ 000280795	JNJ 000309430	JNJTALC000387236
JNJ 000280799	JNJ 000338317	JNJTALC000387334
JNJ 000280804	JNJ 000347203	JNJTALC000387515
JNJ 000280806	JNJ 000347440	JNJTALC000387656
JNJ 000280818	JNJ 000577860	JNJTALC000387660
JNJ 000280819	JNJ 000577861	JNJTALC000387698
JNJ 000280821	JNJ 000577862	WTALC00002674
JNJ 000280823	JNJ 000578188	WTALC00002695
JNJ 000280824	JNJ 000578747	WTALC00002712
JNJ 000280825	JNJ 000683572	WTALC00002745
JNJ 000280826	JNJ 000683573	WTALC00002762
JNJ 000280832	JNJ 000683579	WTALC00004583
JNJ 000280834	JNJ 000684541	
JNJ 000280836	JNJTALC000071234	
JNJ 000280838	JNJTALC000071235	
JNJ 000280839	JNJTALC000071242	
JNJ 000280843	JNJTALC000071243	
JNJ 000280844	JNJTALC000071244	
JNJ 000280845	JNJTALC000071245	
JNJ 000280846	JNJTALC000071247	
JNJ 000280847	JNJTALC000071250	

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Tester:	Bain Environmental
Test Material/Production Stage:	Ground Talc Ore
Testing Frequency/Date Range:	Monthly, 1996 - 1998
Test Results Reviewed:	27 monthly samples
Results:	Two chrysotile fibers found but below detection limit; subsequent retest failed to find chrysotile (<i>See</i> IMERYS-MDL-AB 0006077; JNJ 000280761). All other tests detected no asbestiform minerals.
Example Test Result Reference:	JNJ 000280751
Example Test Result:	

Bain Environmental, Inc.

20 July 1997

Mr. Tim Hicks
Luzenac America, Inc.
West Windsor Laboratory
P.O. Box 680
Windsor, VT 05089

Subject: TEM Analysis of LAI 97-5 and LAI 97-6
for Asbestos Minerals

Re: Bain Project No.: BE-970718142

Dear Mr. Hicks:

We have completed the transmission electron microscopy (TEM) analysis of two talc samples labelled "LAI 97-5" and "LAI 97-6" for asbestos mineral content. We received the samples on 18 July 1997 in good condition. The work was completed under your purchase order number QC39934W.

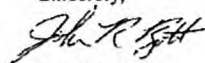
The analysis was completed according to our standard operating procedure *A Standard TEM Procedure for Identification and Quantitation of Asbestiform Minerals in Talc* (Kremer, 1990). According to the methodology, chrysotile and amphibole asbestos mineral identifications are made using morphology, selected area electron diffraction (SAED) and energy-dispersive x-ray spectroscopy (EDS) analyses. Examination was conducted using a JEOL 1200 TEM, operating at 120KV and magnifications up to 20,000 X.

Using this test method, we detected no asbestiform minerals in the samples. A summary of the results are provided in Table I.

As we do not have the facilities to store the samples indefinitely; if you would like to have them returned, please notify us within 30 days. Otherwise, after 30 days, the samples will be discarded.

Thank you for consulting Bain Environmental, Inc. If you have any questions regarding the analysis, please contact our office at (630) 769-0400.

Sincerely,



John R. Roth
Electron Microscopist

*Confidential***List of Test Results Reviewed:**

IMERYS 099374
IMERYS 099377
IMERYS 099380
IMERYS 230250
IMERYS 230255
IMERYS-MDL-AB 0006077
JNJ 000280750
JNJ 000280751
JNJ 000280754
JNJ 000280755
JNJ 000280756
JNJ 000280757
JNJ 000280759
JNJ 000280761
JNJ 000280761
JNJ 000280765
JNJ 000280766
JNJ 000280772
JNJ 000280773

Confidential

Tester:	IMERYS
Test Material/Production Stage:	Ground Talc Ore
Testing Frequency/Date Range:	Monthly and Per Shipment, 2003 - 2020
Test Results Reviewed:	93 monthly composite samples
Results:	Zero asbestos structures found in all results reviewed
Example Test Result Reference:	IMERYS-MDL-AB_0010461
Example Test Result:	



Luzenac • 345 Inverness Drive South • Suite 310 • Centennial, CO 80112 • (303) 643-0451 • Fax: (303) 643-0446

CONFIDENTIAL**ORE CERTIFICATION REPORT**

Date: 3-Nov-05

To: John Poston

Reported by: J. Pier, H. Rothschof

Copy: D. Crouse, E. Ronald, S. Wulf, R. J. Zazenski

Results:

The following composite ore sample, representing the September 2005 Guangxi 2A shipment to Houston, was analyzed by X-ray diffraction (XRD) for the presence of amphibole minerals and quartz. The sample was also analyzed by transmission electron microscopy (TEM) for the presence of asbestiform minerals. The requested tests are in partial fulfillment of specifications required by [REDACTED].

	Guangxi 2A Composite - ACM September 2005 Shipment (MV Pacific Acadian) A05508-1
Analytical Lab Code:	
Specification:	
<i>Initial Ore Results – After Grinding (1B)</i>	
3.14 Percent Fibrous Amphibole (CTFA J4-1)	
Part A (X-ray Diffraction):	None detected
Part B (Optical Microscopy):	Not required
3.15 Percent Free Crystalline Silica Quartz (CTFA Method J6-1) (X-Ray Diffraction)	None detected
<i>TEM Results – After Grinding (1C)</i>	
3.16 Asbestos by Transmission Electron Microscope (TM 7024)	None detected

*Confidential***List of Test Results Reviewed:**

IMERYYS 471832	IMERYYS-MDL-AB_0010658
IMERYYS 479587	IMERYYS-MDL-AB_0010671
IMERYYS 479588	IMERYYS-MDL-AB_0010720
IMERYYS-MDL-AB_0010469	IMERYYS-MDL-AB_0012007
IMERYYS-MDL-AB_0010509	JNJTALC001335657
IMERYYS-MDL-AB_0010446	JNJTALC001335671
IMERYYS-MDL-AB_0010450	JNJTALC001335675
IMERYYS-MDL-AB_0010451	JNJTALC001335680
IMERYYS-MDL-AB_0010452	JNJTALC001341125
IMERYYS-MDL-AB_0010453	JNJTALC001341136
IMERYYS-MDL-AB_0010454	JNJTALC001341197
IMERYYS-MDL-AB_0010455	JNJTALC001341226
IMERYYS-MDL-AB_0010459	JNJTALC001430360
IMERYYS-MDL-AB_0010461	
IMERYYS-MDL-AB_0010462	
IMERYYS-MDL-AB_0010463	
IMERYYS-MDL-AB_0010464	
IMERYYS-MDL-AB_0010465	
IMERYYS-MDL-AB_0010466	
IMERYYS-MDL-AB_0010467	
IMERYYS-MDL-AB_0010468	
IMERYYS-MDL-AB_0010469	
IMERYYS-MDL-AB_0010470	
IMERYYS-MDL-AB_0010471	
IMERYYS-MDL-AB_0010472	
IMERYYS-MDL-AB_0010473	
IMERYYS-MDL-AB_0010501	
IMERYYS-MDL-AB_0010509	
IMERYYS-MDL-AB_0010519	
IMERYYS-MDL-AB_0010535	
IMERYYS-MDL-AB_0010536	
IMERYYS-MDL-AB_0010552	
IMERYYS-MDL-AB_0010565	
IMERYYS-MDL-AB_0010582	
IMERYYS-MDL-AB_0010587	
IMERYYS-MDL-AB_0010588	
IMERYYS-MDL-AB_0010591	
IMERYYS-MDL-AB_0010598	
IMERYYS-MDL-AB_0010599	
IMERYYS-MDL-AB_0010636	
IMERYYS-MDL-AB_0010650	
IMERYYS-MDL-AB_0010657	

Confidential

Tester:	Johnson & Johnson
Test Material/Production Stage:	Finished Talc
Testing Frequency/Date Range:	Weekly/Bi-weekly/Quarterly, 1972 - 1987 and 1990 - 1993
Test Results Reviewed:	560 composite samples
Results:	No asbestiform minerals were detected in any results reviewed
Example Test Result Reference:	JNJ 000237334
Example Test Result:	

Johnson & Johnson
PRODUCTS INC.

NEW BRUNSWICK, N. J.
August 30, 1983

PROJECT: 6995.01

SUBJECT: EXAMINATION OF VERMONT 66 TALC
BY X-RAY DIFFRACTION AND
DIFFERENTIAL THERMAL ANALYSIS

TO: Mr. J. Molnar

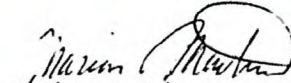
FROM: Ms. Marion Martin

The following bi-weekly composite samples of Vermont 66 talc have been analyzed by (1) continuous scanning X-ray diffraction for qualitative mineralogical composition, (2) slow scanning X-ray diffraction for the presence of amphibole minerals (CTFA Method J4-1), and (3) presence of free crystalline silica (quartz) by X-ray diffraction (CTFA Method J6-1). As of August of 1982, analysis for serpentine minerals is now performed on quarterly composite samples by W. C. McCrone Associates, Chicago, utilizing transmission electron microscopy (TEM).

28 March - 3 April	25 - 29 April
4 - 8 April	2 - 6 May
11 - 15 April	9 - 13 May
18 - 22 April	16 - 20 May

The samples appear to be typical of Vermont 66 talc samples previously examined.

In accordance with the above methods, no quartz or asbestiform amphibole minerals were detected in these samples.


Marion Martin
Analytical Laboratories

*Confidential***List of Test Results Reviewed:**

JNJ 000223427	JNJ 000266719
JNJ 000231479	JNJ 000266720
JNJ 000237249	JNJ 000268548
JNJ 000237285	JNJ 000277537
JNJ 000237293	JNJ 000277555
JNJ 000237310	JNJ 000285133
JNJ 000237318	JNJ 000285248
JNJ 000237322	JNJ 000285249
JNJ 000237332	JNJ 000324759
JNJ 000237334	
JNJ 000237336	
JNJ 000237341	
JNJ 000237345	
JNJ 000237369	
JNJ 000245520	
JNJ 000245526	
JNJ 000245537	
JNJ 000251854	
JNJ 000251923	
JNJ 000252010	
JNJ 000252328	
JNJ 000264673	
JNJ 000264721	
JNJ 000264725	
JNJ 000264728	
JNJ 000264733	
JNJ 000264742	
JNJ 000264752	
JNJ 000265139	
JNJ 000265173	
JNJ 000266679	
JNJ 000266687	
JNJ 000266688	
JNJ 000266691	
JNJ 000266692	
JNJ 000266693	
JNJ 000266694	
JNJ 000266698	
JNJ 000266699	
JNJ 000266700	
JNJ 000266701	
JNJ 000266702	
JNJ 000266706	
JNJ 000266708	
JNJ 000266710	
JNJ 000266711	
JNJ 000266713	

Confidential

Tester:	ES Laboratories
Test Material/Production Stage:	Finished Talc
Testing Frequency/Date Range:	Weekly/Bi-weekly/Tri-weekly/Monthly/Quarterly, 1987 - 1990
Test Results Reviewed:	86 composite samples
Results:	No asbestos minerals were detected in any tests reviewed.
Example Test Result Reference:	JNJ 000246218
Example Test Result:	

ES**LABORATORIES****TALC ANALYSIS**

CUSTOMER: Johnson & Johnson B.P.Division		DATE: 8/27/87	
REPORT NO. ES#8351		P.O. B8612-00079	
		INVOICE NO. J-4029	
Sample no:	"3 Aug. to 12 Aug. 1987"		
AMPHIBOLE GROUP	not detected		
SERPENTINE GROUP	not detected		
α-QUARTZ	not detected		
CHLORITE	1.5%		
DOLOMITE	not detected		
MAGNESITE	0.5%		
TALC	95-97%		
Other Minerals	0.5-1.0%		
MICROSCOPY REQUIRED...	No		
FIBROUS*			

* As defined by OSHA Standard Bulletin 1910.93a, No. 20.
ALL TALC SAMPLES ANALYSED BY THE CTFA J4-1 METHOD.

Amphibole Group: Tremolite, Actinolite and Anthophyllite.
Serpentine Group: Chrysotile

ANALYST: 

*Confidential***List of Test Results Reviewed:**

JNJ 000060818	JNJ 000266651
JNJ 000246159	JNJ 000266656
JNJ 000246164	JNJ 000284272
JNJ 000246182	JNJ 000284275
JNJ 000246190	JNJ 000284303
JNJ 000246218	JNJ 000284306
JNJ 000246226	JNJ 000284309
JNJ 000246245	JNJ 000284337
JNJ 000246250	JNJTALC000217062
JNJ 000246255	JNJTALC000217067
JNJ 000246261	JNJTALC000217111
JNJ 000246268	JNJTALC000217126
JNJ 000246272	JNJTALC000217155
JNJ 000246276	JNJTALC000217164
JNJ 000246280	JNJTALC000217169
JNJ 000246289	JNJTALC000217211
JNJ 000246294	JNJTALC000217215
JNJ 000246304	JNJTALC000217256
JNJ 000246309	JNJTALC000217264
JNJ 000246314	JNJTALC000217276
JNJ 000246319	JNJTALC001272503
JNJ 000246329	JNJTALC000217284
JNJ 000266519	
JNJ 000266524	
JNJ 000266529	
JNJ 000266534	
JNJ 000266539	
JNJ 000266544	
JNJ 000266549	
JNJ 000266554	
JNJ 000266559	
JNJ 000266564	
JNJ 000266569	
JNJ 000266587	
JNJ 000266592	
JNJ 000266597	
JNJ 000266602	
JNJ 000266607	
JNJ 000266612	
JNJ 000266617	
JNJ 000266622	
JNJ 000266627	
JNJ 000266632	
JNJ 000266637	
JNJ 000266642	
JNJ 000266647	

Confidential

Tester:	IMERYS
Test Material/Production Stage:	Finished Talc
Testing Frequency/Date Range:	Varied, 1993 - 2003
Test Results Reviewed:	124 samples
Results:	No asbestiform minerals were detected in any results reviewed
Example Test Result References:	IMERYS 051425
Example Test Results:	



Luzenac America Technical Center • 8985 East Nichols Avenue • Englewood, CO 80112 • (303) 643-0451 • Fax: (303) 799-8926

CONFIDENTIAL**PRODUCT CERTIFICATION REPORT**

Date: July 15, 1994

Attention: Regina Gallagher
Johnson and Johnson Consumer Products
Grandview Road
Skillman, NJ 08558

Reported by: Julie D. Harlan *Julie Harlan*

Copy: Tim Hicks, Joan Johnson, Mike Keener, Bill Sevy

Product	Date Milled	% Amphibole	% Quartz	% Chrysotile
Grade 66 - Silo 5	April 24 - May 2, 1995	nd	nd	nd
Grade 66 - Silo 6	May 12 - May 18, 1995	nd	nd	nd

nd: not detected

nq: mineral concentration < 0.1% - not quantifiable

* : X-ray diffraction results were verified by polarized light microscopy

No asbestiform minerals were detected.

*Confidential***List of Test Results Reviewed:**

IMERYS 010592	JNJ 000280881
IMERYS 015669	JNJ 000280882
IMERYS 015687	JNJ 000280883
IMERYS 051413	JNJ 000280884
IMERYS 051415	JNJ 000577843
IMERYS 051417	JNJ 000578019
IMERYS 051418	JNJ 000578021
IMERYS 051419	JNJ 000578022
IMERYS 051421	JNJ 000578023
IMERYS 051422	JNJ 000578025
IMERYS 051423	JNJ 000578026
IMERYS 051424	JNJ 000578028
IMERYS 051425	JNJ 000578029
IMERYS 051426	JNJ 000578030
IMERYS 051427	JNJ 000683560
IMERYS 051428	JNJ 000683561
IMERYS 051429	JNJ 000683566
IMERYS 051430	JNJ 000683571
IMERYS 051434	JNJ 000683573
IMERYS 051435	JNJ 000683574
IMERYS 051436	JNJ 000683575
IMERYS 051437	JNJ 000683576
IMERYS 051438	JNJ 000683577
IMERYS 051439	JNJ 000683578
IMERYS 051440	JNJ 000683580
IMERYS 051441	JNJ 000683948
IMERYS 051442	JNJTALC000023169
IMERYS 051443	JNJTALC000071281
IMERYS 051444	JNJTALC000071282
IMERYS 051445	JNJTALC000376771
IMERYS 051446	
IMERYS 051447	
IMERYS 051448	
IMERYS 213434	
IMERYS 340515	
IMERYS 432437	
IMERYS 475724	
IMERYS 475831	
IMERYS 477382	
JNJ 000280870	
JNJ 000280871	
JNJ 000280872	
JNJ 000280879	
JNJ 000280880	

Confidential

Tester:	The McCrone Group
Test Material/Production Stage:	Finished Talc
Testing Frequency/Date Range:	Quarterly, 1977 - 1996
Test Results Reviewed:	51 quarterly composite samples
Results:	Chrysotile found in 1983 Q3 sample, but suspected contamination and subsequent retest failed to confirm finding (See JNJALC000070307). All other tests detected no asbestiform minerals.
Example Test Result Reference:	JNJ 000266448
Example Test Result:	



mcCrone environmental services, inc.
1412 OAKBROOK DRIVE • SUITE 100
NORCROSS, GA 30093 • 404-368-9600

5 December 1988

Johnson & Johnson
Baby Products Company
Skillman, NJ 08558

Attention: Mr. Joseph Schmidt

Subject: Analysis of One Talc Sample for Asbestos
Mineral Content by Transmission Electron
Microscopy (TEM)

Re: McCrone Project No. ME-5667

Dear Mr. Schmidt:

McCrone Environmental Services, Inc. has completed the analysis of the talc sample we received from your office on 16 November 1988. The sample was labelled: No. 25-HV66.

The sample was prepared and analyzed following our TEM laboratory's standard operating procedure for powdered talc, which is very similar to test method no. 7024A.

No asbestos minerals were identified in the sample.

Thank you for consulting McCrone Environmental Services, Inc. If you have any questions concerning these results, please contact our office.

Sincerely,

E. Kent Sprague
Electron Microscopist

Joseph A. Krewer
Manager, Electron Optics Group

*Confidential***List of Test Results Reviewed:**

IMERYS 475969	JNJ 000266479
IMERYS 475978	JNJ 000266498
JNJ 000065570	JNJ 000266499
JNJ 000223429	JNJ 000266500
JNJ 000237227	JNJ 000266503
JNJ 000237229	JNJ 000266504
JNJ 000237232	JNJ 000266670
JNJ 000237240	JNJ 000285111
JNJ 000237242	JNJ 000285131
JNJ 000237243	JNJ 000285154
JNJ 000237244	JNJ 000285446
JNJ 000237245	JNJ 000300405
JNJ 000237246	JNJ 000324762
JNJ 000237247	JNJ 000324795
JNJ 000237248	JNJ 000347015
JNJ 000237272	JNJ 000375817
JNJ 000237275	JNJ 000375819
JNJ 000237278	JNJ 000375820
JNJ 000237281	JNJ 000375821
JNJ 000237291	JNJ TALC000070307
JNJ 000237298	JNJ TALC001272572
JNJ 000237299	
JNJ 000237304	
JNJ 000237316	
JNJ 000237321	
JNJ 000237325	
JNJ 000237331	
JNJ 000237340	
JNJ 000237344	
JNJ 000237347	
JNJ 000239630	
JNJ 000239634	
JNJ 000239635	
JNJ 000239636	
JNJ 000239637	
JNJ 000239823	
JNJ 000239824	
JNJ 000239825	
JNJ 000245524	
JNJ 000245548	
JNJ 000246135	
JNJ 000246180	
JNJ 000264734	
JNJ 000266375	
JNJ 000266428	
JNJ 000266448	

Confidential

Tester:	Bain Environmental
Test Material/Production Stage:	Finished Talc
Testing Frequency/Date Range:	Quarterly, 1996 - 2003
Test Results Reviewed:	18 quarterly composite samples
Results:	No asbestiform minerals were detected in any tests reviewed.
Example Test Result Reference:	IMERYS 476829
Example Test Result:	

Bain Environmental, Inc.

23 January 1999

Ms. Julie Harlan
Luzenac America, Inc.
8985 East Nichols Avenue
Englewood, CO 80112

Subject: TEM Analysis of Talc A98354
for Asbestos Mineral Content

Re: Bain Project No.: BE-981231496

Dear Ms. Harlan:

We have completed the transmission electron microscopy (TEM) analysis of one talc sample labeled "A98354" for asbestos mineral content. We received the sample on 31 January 1998 in good condition. The work was completed under your written authorization of 22 December 1998.

The analysis was completed according to Johnson & Johnson Test No. TM7024, "Analysis of Powdered Talc for Asbestiform Minerals by TEM, (REV: 08/21/95)." According to the methodology, chrysotile and amphibole asbestos mineral identifications are made using morphology, selected area electron diffraction (SAED) and energy-dispersive x-ray spectroscopy (EDS) analyses. Examination was conducted using a JEOL 100CX TEM, operating at 100KV and magnifications up to 20,000 X.

We detected no asbestiform minerals in the sample. A summary of the results are provided in Table I. An individual sample report is also attached

We do not have the facilities to store the sample indefinitely. If you would like to have it returned, please notify us within 30 days. After 30 days, the sample will be discarded.

Thank you for consulting Bain Environmental, Inc. If you have any questions regarding the analysis, please contact our office at (630) 769-0400.

Sincerely,


John R. Roth
Electron Microscopist

*Confidential***List of Test Results Reviewed:**

IMERYS 342519
IMERYS 472069
IMERYS 475449
IMERYS 475529
IMERYS 475702
IMERYS 475840
IMERYS 476570
IMERYS 476592
IMERYS 476768
IMERYS 476829
IMERYS 476982
IMERYS 477879
IMERYS 478026
IMERYS 478033
IMERYS 478038
IMERYS 480163
IMERYS 480224
IMERYS 480516

Confidential

Tester:	IMERYS
Test Material/Production Stage:	Finished Talc
Testing Frequency/Date Range:	Monthly, 2009 - 2020
Test Results Reviewed:	133 samples
Results:	No asbestiform minerals were detected in any results reviewed
Example Test Result References:	IMERYS-MDL-AB_0010742
Example Test Results:	



Rio Tinto Minerals • 8051 E. Maplewood Ave • Greenwood Village, CO 80111 • (303) 713-5000 • Fax: (303) 713-5788

TECHNICAL REPORT

To: **Shripal Sharma**

Analytical Project No: **A10633**
Analytical Research No: **AR0023**
Date: **11-Jan-11**

From: **Larry Harrower**
Analytical and Technical Support

Copy: **R. Harrison, A. Kirk, J. Kopp, J. Pier, J. Poston**

Subject: **CTFA-USP XRD ANALYSIS OF HOUSTON COMPOSITES:**
SEPTEMBER 2010

Request:

Product composite samples from September 2010 were sent from Houston to the Technical Center in accordance with the fiber management framework. Additional quartz, amphibole, and serpentine analysis by X-ray diffraction (XRD) in quantitative "slow scan" conditions are being performed conforming with CTFA methods J 6-1 and J 4-1 (A04488, A05403), and USP standards.

Results:

Sample	Composite Date	Analytical Reference No.	% Quartz	% Amphibole
██████████	██████████	██████████	██	██
Grade 25 USP	September 2010	A10633-2	0.1	< 0.5

*Confidential***List of Test Results Reviewed:**

IMERYS 372683	IMERYS 478878
IMERYS 443370	IMERYS 479163
IMERYS 449238	IMERYS 480619
IMERYS 454928	IMERYS 481134
IMERYS 471270	IMERYS 481304
IMERYS 471274	IMERYS 481492
IMERYS 471310	IMERYS 482412
IMERYS 471318	IMERYS 482696
IMERYS 471326	IMERYS 482785
IMERYS 471329	IMERYS 484617
IMERYS 471336	IMERYS 484708
IMERYS 471337	IMERYS 484715
IMERYS 471343	IMERYS 486419
IMERYS 471344	IMERYS 487335
IMERYS 471345	IMERYS 488618
IMERYS 471346	IMERYS 488628
IMERYS 471347	IMERYS 488650
IMERYS 471348	IMERYS 488678
IMERYS 471349	IMERYS 488701
IMERYS 471350	IMERYS 488722
IMERYS 471351	IMERYS 492781
IMERYS 471362	IMERYS 492807
IMERYS 471899	IMERYS 492943
IMERYS 471901	IMERYS-MDL-AB 0010480
IMERYS 471905	IMERYS-MDL-AB 0010483
IMERYS 471907	IMERYS-MDL-AB_0010477
IMERYS 471933	IMERYS-MDL-AB_0010677
IMERYS 471943	IMERYS-MDL-AB_0010742
IMERYS 471951	JNJTALC001334331
IMERYS 471953	JNJTALC001334337
IMERYS 471959	JNJTALC001334340
IMERYS 471965	JNJTALC001334346
IMERYS 471969	JNJTALC001334352
IMERYS 471975	JNJTALC001334358
IMERYS 471982	JNJTALC001334364
IMERYS 471984	JNJTALC001334370
IMERYS 471986	JNJTALC001334376
IMERYS 471988	JNJTALC001334382
IMERYS 471998	JNJTALC001334388
IMERYS 472000	JNJTALC001334394
IMERYS 472020	JNJTALC001334400
IMERYS 472022	JNJTALC001341098
IMERYS 472024	
IMERYS 472028	

Confidential

Tester:	RJ Lee Group
Test Material/Production Stage:	Finished Talc
Testing Frequency/Date Range:	Quarterly, 2010 - 2020
Test Results Reviewed:	40 samples
Results:	No asbestos was detected in any tests reviewed.
Example Test Result Reference:	JNJ 000383338
Example Test Result:	



July 10, 2013

Mr. Donald L. Hicks
Johnson & Johnson Cosmetic Products
Mail Drop SE-122
199 Grandview Road
Skillman, NJ 08558

RE: Analysis of Six Talc Samples (2Q13)
RJ Lee Group Project No. TLH910635

Dear Mr. Hicks:

The analyses of the talc samples received on May 14, 2013 have been completed. These tests were conducted in general accordance with the specifications contained in Johnson & Johnson (J&J) talc specification, RM-008967 (revision 4).

No asbestos was detected in the samples.

Table 1 shows a comparison of the MgO and SiO₂ values as determined using x-ray fluorescence or a chemical digestion procedure. Table 2 shows the preliminary data for "whiteness" derived using three measurement procedures.

Since the sample was not listed as "sanitized talc powder", no microbial testing was performed. Brightness was also not determined on the samples. A detection limit of 1 ppm was used for water-soluble iron. Finally, a detection limit of 0.1% was used for the Crystalline Silica tests.

If you have any questions, please feel free to contact me.

Sincerely,

Drew R. Van Orden, PE
Senior Consulting Scientist
drew@rjlg.com

*Confidential***List of Test Results Reviewed:**

JNJ 000132159
JNJ 000133653
JNJ 000133797
JNJ 000133839
JNJ 000133908
JNJ 000134009
JNJ 000134054
JNJ 000134075
JNJ 000134159
JNJ 000134197
JNJ 000134313
JNJ 000381001
JNJ 000382024
JNJ 000382986
JNJ 000383016
JNJ 000383087
JNJ 000383338
JNJ 000384469
JNJ 000384502
JNJ 000384551
JNJ 000521505
JNJ 000521516
JNJ 000521581
JNJ 000558343
JNJ 000558360
JNJ 000558568
JNJ 000558731
JNJ 000558931
JNJ 000558970
JNJ 000631351
JNJTALC000196139
JNJTALC000196176
JNJTALC000196252
JNJTALC000196576
JNJTALC001054034
JNJTALC001079382
JNJTALC001082577
JNJTALC001083855
JNJTALC001084921
JNJTALC001353867
JNJTALC001389105
JNJTALC001389361
JNJTALC001391321

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Tester:	Johnson & Johnson Worldwide Talc Monitoring Program, The McCrone Group, and EMV Associates
Test Material/Production Stage:	Bottled Talc
Testing Frequency/Date Range:	Yearly, 1975 - 1985, 1993 - 1996, and 1998 - 1999
Test Results Reviewed:	33 samples
Results:	No asbestos was detected in any tests reviewed.
Example Test Result Reference:	JNJTALC000166736
Example Test Result:	

FREEDOM FROM ASBESTOS

BY CTFA METHOD

All talcs passed the freedom from fibrous amphibole

test (CTFA J4-1) as prescribed in the latest issue

of Cosmetic Talc specification by the Cosmetic, Toiletry and Fragrance Association of the U.S.A.

*Confidential***List of Test Results Reviewed:**

JNJ 000061342

JNJ 000089078

JNJTALC000166630

JNJTALC000166674

JNJTALC000166705

JNJTALC000166716

JNJTALC000166736

JNJTALC000166745

JNJTALC000348670

JNJTALC000348694

JNJTALC000348700

JNJTALC000348703

JNJTALC000348794

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Appendix E

Johnson & Johnson's Credo and Organizational Policies and Procedures

1. My initial research involved reviewing internal J&J policies and procedures, as well as internal documents that provided insight into J&J's organizational priorities and described its organizational ethos. Below is a summary of the materials I reviewed and the conclusions that I drew from those materials. While I was not asked to assess J&J's organizational culture per se, it is important to my overall opinions to understand these aspects of the organization in order to assess whether J&J's sensemaking processes were consistent with the organizational incentives, motivations, and actions as codified by these internal documents.

I. JOHNSON & JOHNSON'S ACTIONS ARE CONSISTENT WITH ITS ONGOING ORGANIZATIONAL COMMITMENT TO THE SAFETY OF COSMETIC TALC AND THE WELLBEING OF CONSUMERS

2. I evaluated documents to assess J&J's organizational commitment to the wellbeing of its customers, including documents and testimony that articulated this commitment, and summarize them below. These documents confirm that J&J had a clearly articulated commitment in its Credo. This commitment was operationalized in J&J's policies and procedures, and was top of mind for its employees, including explicit mentions of the Credo in ordinary course of business documents.

A. The Credo

3. J&J's core "values that guide [its] decision-making" are embodied in its Credo, which puts "the needs and well-being of the people [J&J] serves first."¹ Based on my review of the record in this matter, it is my opinion that J&J's sensemaking with regards to talc is consistent with its commitment to the Credo and to the wellbeing of consumers.
4. J&J's Credo was written in 1943, the year in which J&J announced its intention to become publicly traded.² The Credo has been revised several times, but even starting with this 1943 version, J&J's first responsibility has always been to its customers:

"We believe that our *first* responsibility is to our CUSTOMERS - Our products must always be good, and We must strive to make them better at lower costs...."³

¹ "Our Credo," *Johnson & Johnson*, available at <https://www.jnj.com/credo/>. See also "2018 Health for Humanity Report," *Johnson & Johnson*, 2018.

² "Our Credo," *Johnson & Johnson*, available at <https://www.jnj.com/credo/>.

³ "Our Industrial Credo," 1944.

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Even before the original Credo was memorialized, in 1935, Robert Wood Johnson, the author of the original Credo, wrote a pamphlet containing J&J's earliest written expression of their ideals: *Try Reality: A Discussion of Hours, Wages and the Industrial Future*. In this precursor of the original Credo, Mr. Johnson publicly advocated that "businesses had a larger responsibility to society, which included everyone who used their products, their employees and the community."⁴

5. Consistent with what I would expect of an organization that prioritizes consumer wellbeing, J&J recognized that the Credo would need to evolve to stay relevant as time progressed. The fact that J&J has repeatedly invested time and resources into revising the Credo several times demonstrates the value that J&J places on its Credo. These revisions further exhibit J&J's "belief that the document should take into account evolution in language as well as growth and development of the Company."⁵ Despite the evolution of J&J's Credo, the foundational, customer-first principle of the Credo has endured.⁶ This is evident in J&J's Credo today:

"We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality...."⁷

⁴ Janes, Erika, "8 Fun Facts About Our Credo—Johnson & Johnson's Mission Statement," *Johnson & Johnson*, February 5, 2018, available at <https://www.jnj.com/our-heritage/8-fun-facts-about-the-johnson-johnson-credo>.

⁵ "Our Credo," 1948, 1979, 1987.

⁶ As the Credo was revised in 1948 ("We believe that our first responsibility is to the doctors, nurses, hospitals, mothers, and all others who use our products"), 1979 ("We believe our first responsibility is to the doctors, nurses and patients, to mothers, and all others who use our products and services"), and 1987 ("We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services"), J&J's customers have always been its first responsibility. See "Our Credo," 1948, 1979, 1987.

⁷ "Our Credo," *Johnson & Johnson*, available at <https://www.jnj.com/credo/> ("We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit. We are responsible to our employees who work with us throughout the world. We must provide an inclusive work environment where each person must be considered as an individual. We must respect their diversity and dignity and recognize their merit. They must have a sense of security, fulfillment and purpose in their jobs. Compensation must be fair and adequate and working conditions clean, orderly and safe. We must support the health and well-being of our employees and help them fulfill their family and other personal responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide highly capable leaders and their actions must be just and ethical. We are responsible to the communities in which we live and work and to the world community as well. We must help people be healthier by supporting better access and care in more places around the world. We must be good citizens — support good works

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6. J&J's Credo is top-of-mind for employees across all levels of the organization. Employees kept a framed copy of the Credo on their desks and participated in Credo meetings two to three times per year, during which they described how the Credo influenced their recent behavior and decisions.⁸ Furthermore, J&J senior leaders and general employees have taken part in the Credo's evolution over time. For example, in 1975, former Chairman and CEO James Burke organized Credo Challenge meetings so company management could discuss whether the Credo's values were still relevant.⁹ Additionally, in 1985, Mr. Burke launched the Credo Survey process, asking J&J employees worldwide to rate how well J&J was living up to its responsibilities outlined in the Credo.¹⁰ In 2013, J&J conducted another session of Credo Challenges to "nurture a discussion on how Our Credo defines the company in modern times."¹¹ In 2019, J&J reflected on 75 years of the Credo and stated that the Credo is "the Johnson & Johnson mission statement that guides company thinking to this day, from big-picture deals and acquisitions down to the most basic day-to-day decisions."¹² In a 2021 interview, Dr. Susan Nicholson, then-Vice President of Women's Health in J&J's Office of the Chief Medical Officer, confirmed that J&J continues to actively manage a culture around the

and charities, better health and education, and bear our fair share of taxes. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources. Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed, investments made for the future and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.").

⁸ See June 4, 2020 Interview of Dr. John Hopkins.

⁹ See Janes, Erika, "8 Fun Facts About Our Credo—Johnson & Johnson's Mission Statement," *Johnson & Johnson*, February 5, 2018, available at <https://www.jnj.com/our-heritage/8-fun-facts-about-the-johnson-johnson-credo>. The result of these meetings was "a resounding yes! As a result, the company's leaders came out of the meetings even more committed to the document's timeless values."

¹⁰ See Janes, Erika, "8 Fun Facts About Our Credo—Johnson & Johnson's Mission Statement," *Johnson & Johnson*, February 5, 2018, available at <https://www.jnj.com/our-heritage/8-fun-facts-about-the-johnson-johnson-credo>.

¹¹ See Janes, Erika, "8 Fun Facts About Our Credo—Johnson & Johnson's Mission Statement," *Johnson & Johnson*, February 5, 2018, available at <https://www.jnj.com/our-heritage/8-fun-facts-about-the-johnson-johnson-credo>.

¹² See Chatterjee, Camille, "133 Years of Innovative Credo-Driven Decisions That Have Made Johnson & Johnson the Healthcare Leader It Is Today" *Johnson & Johnson*, January 22, 2019, available at <https://www.jnj.com/our-heritage/timeline-of-johnson-johnson-credo-driven-decisions>.

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Credo.¹³ Even with respect to the recent voluntary recall, the Credo guided J&J's decision to recall the product out of an abundance of caution.¹⁴

B. Organizational Policies and Procedures

7. Consistent with the Credo and the organization's stated commitment to consumer wellbeing and product safety, J&J ensures that its employees and suppliers adhere to these long-standing principles through organizational policies and procedures.
8. In 2017, J&J circulated "Responsibility Standards for Suppliers." These standards were developed to govern J&J's selection of suppliers that operate in a manner consistent with its guiding principles such as providing "goods and services that consistently meet customers' needs, are safe for their intended use and perform as intended." Among other requirements, suppliers must "[e]stablish and maintain Quality controls to protect the integrity of the goods; [notify J&J] of proposed changes to specifications, methods, suppliers, materials/components, manufacturing/supply process, manufacturing location or equipment in order to determine impact on the Johnson & Johnson Company's Product; [and permit] the relevant Johnson & Johnson Company or an authorized delegate to conduct Quality audits of the facilities, systems and/or documents related to the goods and services provided, and promptly provide responses and take corrective actions to remedy any observations cited."¹⁵ J&J also put in place a system for assessing and monitoring suppliers, which established routine risk-based assessments and commensurate levels of oversight of suppliers.¹⁶
9. Prior to 2017 J&J had distributed similar versions of these supplier responsibility standards,¹⁷ and J&J's commitment to upholding high quality standards has been on display for decades. For example, J&J has maintained strict specifications, with either pass or fail standards, for its cosmetic talc since the 1940s, thereby ensuring that raw

¹³ See February 5, 2021 Interview of Dr. Susan Nicholson. Dr. Nicholson has held several leadership positions at J&J related to consumer safety. These include Pharmacovigilance Strategy Leader in Janssen Pharmaceuticals' Scientific Affairs department, Vice President of Safety Operations and Compliance in J&J's Medical Devices and Diagnostics department, and Vice President of Safety Surveillance and Risk Management in J&J's Office of Consumer Medical Safety. See Undated – DX D25.

¹⁴ See, e.g., 2019.10.30 – JNJALC001321452 at 453 ("The safety of those who use our products is our top priority and every decision we make is grounded in Our Credo responsibilities. Today I want to provide you with an update on our US single lot recall of Johnsons Baby Powder."); 2019.10.25 – JNJALC001327882 at 885 (Bernstein analyst report noting that the "October 18th recall feels like a similar decision made out of an abundance of caution and given how important JNJ's credo is to employees it is not hard to imagine that management hoped to live up to the example set by James Burke.").

¹⁵ "Responsibility Standards for Suppliers," *Johnson & Johnson*, 2017.

¹⁶ See, e.g., 2017.05.19 – JNJALC001430068 at 071 (Global Standard Operating Procedure: Risk Categorization Assessment and Performance Monitoring for Direct Material Suppliers and External Manufacturers).

¹⁷ See, e.g., "Responsibility Standards for Suppliers," *Johnson & Johnson*, 2012.

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materials meet quality standards.¹⁸ Additionally, J&J implemented stringent requirements on its third-party talc suppliers. Examples of these requirements include standard operating procedures related to supplier selection, supplier measuring and monitoring, external auditing of suppliers, and risk characterization of suppliers.¹⁹

10. J&J continues to articulate and demonstrate that product safety is essential to its business. On its website, J&J specifies a five-step safety assurance process: sourcing raw materials, assessing ingredients, testing formulas, monitoring real life use, and ongoing evaluation.²⁰ Additionally, J&J states, “Our safety assurance process is one of the most stringent in the world, ensuring the safety and quality of every baby and beauty personal care product we make. ... Because science is constantly evolving, we monitor the findings of the latest research and update our products when we feel there is an opportunity to improve a product. Similarly, we stay connected with consumers to help identify opportunities for further improvements and enhancements.”²¹ Historically, J&J has done just that, continuously re-evaluating its baby powder and updating the formula accordingly.²² For example, in response to an accusation of danger associated with boric acid in the 1950s, J&J removed the ingredient from its baby powder formula.²³ J&J also expected regional regulatory affairs leaders to proactively communicate with local health authorities on talc related developments.²⁴ J&J continues to have a designated Safety Officer for each product, including baby powder, who is responsible for internal and external concerns and issues and who is responsible for investigating any instance of nonconformance with safety standards.²⁵

¹⁸ See 1949.05.20 – JNJ TALC000026016; June 4, 2020 Interview of Dr. John Hopkins.

¹⁹ See, e.g., 2015.05.15 – JNJ TALC000238345 (2015 SOP: Purchasing Control Processes: North America Supplier Selection, Supplier Measuring and Monitoring and Supplier Disengagement for Direct Material); 2016.02.18 – JNJ TALC000238361 (2016 SOP: External Audit Procedure for Source Quality Suppliers); 2016.01.01 – JNJ TALC000238454 (2016 SOP: Risk Categorization, Assessment and Performance Monitoring for Direct Material Suppliers and External Manufacturers).

²⁰ “Fast facts: The Johnson & Johnson Safety Process,” *Johnson & Johnson*, available at <https://www.jnj.com/our-company/fast-facts-the-johnson-johnson-safety-process>.

²¹ “Fast facts: The Johnson & Johnson Safety Process,” *Johnson & Johnson*, available at <https://www.jnj.com/our-company/fast-facts-the-johnson-johnson-safety-process>.

²² See, e.g., 1966.07.13 – DX7731 (historical survey listing all changes to the J&J baby powder formula between 1907 and 1955).

²³ See 1969.04.15 – JNJ 000087991 at 992; 1966.07.13 – DX7731 at 3.

²⁴ See 2019.10.18 – JNJ TALC001300939.

²⁵ See February 5, 2021 Interview of Dr. Susan Nicholson.

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11. Over the past decade, J&J has taken additional steps to strengthen its organizational commitment to product safety.²⁶ This includes the 2013 establishment of the Office of the Chief Medical Officer, an independent group “whose job it is to understand all of the scientific literature and make an assessment to drive the assessment of the safety of [its] products.”²⁷ With a vision “to lead J&J to be the most trusted company by assuring patient and consumer safety is the highest priority, and keeping patient and customer centered, objective decision making at the heart of all [it does],” J&J created the role of Chief Medical Officer with a “focus on a patient and consumer centered approach to safety, transparency and collaboration.”²⁸ The office of the Chief Medical Officer is responsible for reviewing “the safety data [J&J] had in-house about talcum powder, and they do that in an ongoing way for all of [J&J’s] products,” including talc.²⁹ J&J has also recently introduced a Global Ingredient Steering Committee committed to ensuring consumer product ingredient safety.³⁰ Currently, J&J has a Quality Group, a Medical Safety Group, and a Regulatory Group, each of which manages product testing and audits to ensure compliance with J&J’s standards.³¹ Further, J&J codifies its processes through worldwide and regional standard operating procedures that make explicit how the organizational commitment to quality and safety is enacted in day-to-day operations.³² J&J also has an Ethics Committee, external Advisory Board, and regular outreach to external experts that are resources and interact as needed with these groups on complex issues such as the allegations of asbestos in talc.³³

²⁶ I understand that prior to the more recent developments described here, and at least since the early 1970s, research, development, and product line leadership have been actively engaged in product safety discussions and decisions as part of ongoing operations. Within J&J, regular meetings and communications ensured that multiple perspectives across the various internal stakeholders were shared, and that there was agreement among the various stakeholders during decision making processes. *See* June 4, 2020 Interview of Dr. John Hopkins.

²⁷ Deposition of Joanne Waldstreicher, M.D., April 19, 2017 (hereafter “Waldstreicher Deposition”), 184:12-17, 233:2-4. *See also* “Scientific Excellence, Bioethics and Values-Driven Decision-Making,” *Johnson & Johnson*, May 10, 2017, available at <https://www.jnj.com/office-chief-medical-officer/scientific-excellence-bioethics-and-values-driven-decision-making>; Exhibit 1 to the Waldstreicher Deposition.

²⁸ *See* Exhibit 1 to the Waldstreicher Deposition at 6, 9.

²⁹ *See* Waldstreicher Deposition, 313:12-17. *See also* February 5, 2021 Interview of Dr. Susan Nicholson.

³⁰ *See* “2018 Health for Humanity Report,” *Johnson & Johnson*, 2018.

³¹ *See* February 5, 2021 Interview of Dr. Susan Nicholson.

³² *See, e.g.*, 2017.05.19 – JNJALC001430068 and 2019.09.08 – JNJALC001396675 (Global Standard Operating Procedure: Risk Categorization Assessment and Performance Monitoring for Direct Material Suppliers and External Manufacturers); 2018.09.08 – JNJALC001415261 (NA - Fort Washington Standard Operating Procedure: Regulatory Affairs Management and Tracking Health Authority Spontaneous Safety Queries and Commitments made to Health Authorities); 2018.09.14 – JNJALC001393757 (Global Standard Operating Procedure: Product Risk Management); 2018.10.29 – JNJALC001347097 (Global Standard Operating Procedure: Field Actions); 2019.06.27 – JNJALC001347059 (Global Standard Operating Procedure: End-to-End Lifecycle Management for Investigation, Non-Conformance and Corrective Action/Preventive Action).

³³ *See* February 5, 2021 Interview of Dr. Susan Nicholson.